

EXHIBIT 11

RIVKIN RADLER LLP

IN THE UNITED STATES DISTRICT COURT

TEVA BRANDED PHARMACEUTICAL
PRODUCTS R&D, INC., AND NORTON
(WATERFORD) LTD.,

V.

CIPLA LTD, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., AND AUROLIFE PHARMA LLC, DEFENDANTS.

**DEFENDANTS' PRELIMINARY CLAIM CONSTRUCTIONS AND
SUPPORTING EVIDENCE PURSUANT TO L. PAT. R. 4.2**

Pursuant to Local Patent Rules 4.2(a)-(b) and the Court’s February 4, 2021 Amended Pretrial Scheduling Order (D.I. 41), Defendants Cipla Ltd. (“Cipla”) and Aurobindo Pharma Ltd. Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC (“Aurobindo”) (collectively, “Defendants”) provide their preliminary proposed claim constructions and supporting evidence for certain terms of the asserted claims of U.S. Patent Nos. 9,463,289; 9,808,587; 10,086,156;

10,561,808; and 10,695,512 (collectively, “the Patents-in-Suit”).¹ This disclosure of preliminary proposed constructions and supporting evidence is based on information presently available to, and known by, Defendants. Defendants note that, as of this date, Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively “Plaintiffs”) have not completed their production of documents and other discoverable information.

Defendants reserve the right to, inter alia, correct, modify, amend, and/or supplement its disclosure of preliminary proposed constructions and supporting evidence as the case proceeds, including, but not limited to, in response to Plaintiffs’ proposed claim construction(s), Plaintiffs’ identification and/or designation of intrinsic or extrinsic evidence, or the parties’ L. Pat. R. 4.2(d) meet and confer conference.

To the extent a preliminary construction for a claim term is not being proposed herein, Defendants understand that the term should be given its plain and ordinary meaning to a person of ordinary skill in the art at the relevant time, and therefore no construction by the Court is necessary at this time. To the extent that Plaintiffs propose a construction for a term that differs from Defendants’ understanding of the plain and ordinary meaning of such term, Defendants reserve the right to offer alternative constructions. To the extent Plaintiffs propose a construction for any portion of any claim term identified herein, Defendants reserve the right to propose separate constructions for such portions of such claim terms in addition to, or in the alternative to, the preliminary proposed constructions set forth herein. Additionally, to the extent Defendants propose

¹ Plaintiffs have requested that Defendants stipulate to the dismissal of U.S. Patent Nos. 10,022,509 and 10,022,510 (collectively, “the Tape Patents”). Stipulations between Aurobindo and Plaintiffs and Cipla and Plaintiffs have been filed dismissing these patents. Dkt. Nos. 89 and 90. However, the Court has not yet entered the stipulations. Defendants reserve the right to identify terms from the Tape Patents and offer constructions for any such terms if the patents are not dismissed from the case.

a construction herein, including the plain and ordinary meaning, of a claim term identified by any party for construction, Defendants do so without prejudice to (and in the alternative to) any indefiniteness defense, under 35 U.S.C. § 112. To the extent Plaintiffs cite to evidence, either intrinsic or extrinsic, in support of Plaintiffs' proposed constructions or in opposition to Defendants' proposed constructions, Defendants reserve the right to rely on any such evidence, both in support of Defendants' proposed constructions or in opposition to Plaintiffs' proposed constructions.

Defendants reserve the right to amend and/or supplement this disclosure. Furthermore, Defendants reserve the right to amend and/or supplement this disclosure when and if additional information becomes available and/or in the event it appears that the parties' understandings of the plain and ordinary meaning of any term are materially different. Defendants further reserve the right to raise any and all issues regarding claim construction during the course of this litigation and/or on appeal should it appear that the parties' understandings of the plain and ordinary meaning of any term in the asserted claims are materially different.

Defendants disclose the following preliminary proposed constructions and supporting evidence:

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"actuation member"	'289 Patent: 1, 3 '587 Patent: 1, 3, 11, 12, 13 '156 Patent: 13	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 5:26-34 • 6:30-33 • 7:20-30 • 12:18-23 • 12:38-13:2 • 13:14-19 • 14:40-15:32 • 15:49-53 • 16:9-14 • Figs. 10C-10E 	<u>Extrinsic Evidence:</u> Dictionary of Mechanical Engineering, 4 th Edition, G.H.F. Naylor, George Newnes Ltd, 1996 ("actuator") at 3. New Oxford American Dictionary, 3 rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("actuate") at 16. Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other

² As the Patents-in-Suit all share a specification, citations to the specification in this chart are to U.S. Patent No. 9,463,289

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				intrinsic evidence, and the parties' extrinsic evidence.
"inner wall"	'289 Patent: 1 '587 Patent: 1, 12, 13	"interior wall of the canister housing"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 12:29-37 • Fig. 2 • Fig. 7D 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"cannister support formation"	'289 Patent: 1, 4 '587 Patent: 1, 4	"structure for preventing medicament canister rocking"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 6:44-46 • 15:33-16:3 • Figs. 7C-7D 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"[lying or lie] in a common plane coincident with the longitudinal axis X"	'289 Patent: 1 '587 Patent: 1, 21, 22	"aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, a [canister support formation as construed by Defendants] located directly adjacent to the [actuation member as construed by Defendants], and the [actuation member as construed by Defendants]"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 6:50-58 '289 Patent File History generally, including but not limited to: <ul style="list-style-type: none"> • March 7, 2016 Office Action Response at 6 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"the inner wall through which a portion of the actuation member extends"	'289 Patent: 3 '587 Patent: 3, 13	"the interior wall of the canister housing through which a portion of the [actuation member as construed by Defendants] extends"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 12:38-53 • Figs. 7B-7D 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"positioned at opposite ends of the inside surface of the main body to face each other"	'289 Patent: 7 '587 Patent: 7, 18	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • Fig. 2 • Figs. 7B-7D '289 Patent File History generally, including but not limited to: <ul style="list-style-type: none"> • March 7, 2016 Office Action Response at 6 	<u>Extrinsic Evidence:</u> New Oxford American Dictionary, 3 rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("end") at 572. New Oxford American Dictionary, 3 rd Edition, Stevenson and Lindeberg, Oxford University Press,

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				<p>Inc., 2010 (“opposite”) at 1231.</p> <p>Plaintiffs’ Responses to Invalidity Contentions.</p> <p>Plaintiffs’ Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties’ extrinsic evidence.</p>
“protects against [unwanted actuation of the dose counter/dose count errors] by reducing rocking of the medicament canister relative	<p>’289 Patent: 1</p> <p>’587 Patent: 1, 12</p>	“prevents the medicament canister from changing the height of the [actuation member as construed by Defendants] sufficiently to result in an unwanted dose count, where such change in height is caused by back and forth movement of the medicament canister relative	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 15:33-53 <p>’289 Patent File History generally, including but not limited to:</p> <ul style="list-style-type: none"> • March 7, 2016 Office Action Response at 5-6 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs’ Responses to Invalidity Contentions.</p> <p>Plaintiffs’ Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
to the main body of the inhaler"		to the main body of the inhaler"	<ul style="list-style-type: none"> November 4, 2015 Office Action Response at 6-7 May 20, 2016 Notice of Allowance 	Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"canister housing"	'289 Patent: 1 '587 Patent: 1	"portion of the body into which a medicament canister is inserted"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> 7:7-10 Fig. 1 Fig. 7A 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"main surface of the inner wall"	'289 Patent: 1 '587 Patent: 1	"Surface of the [inner wall as construed by Defendants] surrounding the medicament canister"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • Fig. 1 • Fig. 7C 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"aperture"	'289 Patent: 3 '587 Patent: 3 '512 Patent: 1	"hole"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • Fig. 6B • Figs. 7B-7D • Figs. 8A-B 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"step formed thereon"	'289 Patent: 5 '587 Patent: 5	"A stepwise increase in the extent to which the support rail extends inwardly"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 15:33-16:3 • Fig. 7C 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"inside surface"	'289 Patent: 4 '587 Patent: 4	"interior surface of the canister housing"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • Fig. 1 • Fig. 7C 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"body"	'156 Patent: 1	"body" (plain meaning)	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 6:24-43 • Fig. 1 • Figs. 8A, 8D 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"ratchet wheel"	'156 Patent: 1, 9, 12	"a notched or toothed wheel either held in place or turned by engaging a pawl"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> Fig. 6D 	<p><u>Extrinsic Evidence:</u></p> <p>Dictionary of Mechanical Engineering, 4th Edition, G.H.F. Naylor, George Newnes Ltd, 1996 ("ratchet wheel") at 310.</p> <p>New Oxford American Dictionary, 3rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("ratchet wheel") at 1447.</p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"actuator"	'156 Patent: 1, 2, 12 '512 Patent: 1, 5	"structure arranged to effect movement"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 5:26-34 • 6:30-33 • 7:20-30 • 12:18-23 • 12:38-13:2 • 13:14-19 • 14:40-15:32 • 15:49-53 • 16:9-14 • Figs. 10C-10E 	<p><u>Extrinsic Evidence:</u></p> <p>Dictionary of Mechanical Engineering, 4th Edition, G.H.F. Nayler, George Newnes Ltd, 1996 ("actuator") at 3.</p> <p>New Oxford American Dictionary, 3rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("actuate") at 16.</p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"actuation pawl arranged to engage with a first tooth of the ratchet wheel"	'156 Patent: 1	"structure, integral with or connected to the [actuator as construed by Defendants], adapted to engage with a tooth of the [ratchet wheel as construed by Defendants], driven by movement of the [actuator as construed by Defendants]"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 5:26-34 • 6:30-33 • 7:20-30 • 12:18-23 • 12:38-13:2 • 13:14-19 • 14:40-15:32 • 15:49-53 • 16:9-14 • Figs. 10C-10E 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"count pawl"	'156 Patent: 1, 9	"structure, separate from the [actuation pawl as construed by Defendants], adapted to engage with a second tooth of the [ratchet wheel as construed by Defendants], past which the second tooth of the [ratchet wheel as construed by Defendants] must rotate in order to register a count"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 13:40-15:32 • 14:60-15:3 • Figs. 6D, 6G • Figs. 10A-10F 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"associated with"	'156 Patent: 1	"associated with" (plain meaning)	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 13:40-15:32 • 14:60-15:3 • Figs. 6D, 6G • Figs. 10A-10F 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"first reset position"	'156 Patent: 1	"configuration in which the [actuator pawl as construed by Defendants] is above the [datum plane as construed by Defendants], but closer to the [datum plane as construed by Defendants] than in the [start configuration as construed by Defendants], and is just engaged with one of a tooth of the [ratchet wheel as construed by Defendants]"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 13:40-15:32 • Figs. 10A-10F <p>'156 Patent File History generally including but not limited to:</p> <ul style="list-style-type: none"> • August 22, 2017 Office Action Response at 5-8 • April 20, 2017 Office Action Response at 5-9 • September 9, 2016 Office Action Response at 5-9 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"canister fire sequence"	'156 Patent: 1	"process of ejecting medicament from an inhaler where the [actuator pawl as construed by Defendants]"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p>	<p><u>Extrinsic Evidence:</u></p> <p>New Oxford American Dictionary, 3rd Edition,</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
		follows a particular sequence of movement from the start configuration to the [reset configuration as construed by Defendants], to the [fire configuration as construed by Defendants], to the [count configuration as construed by Defendants], before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the [count pawl as construed by Defendants] is engaged with a tooth of the [ratchet wheel as construed by Defendants] and the [actuator pawl as construed by Defendants] is spaced from the [ratchet wheel as construed by Defendants].”	<ul style="list-style-type: none"> • 13:40-15:32 • Figs. 10A-10F ’156 Patent File History generally including but not limited to: <ul style="list-style-type: none"> • August 22, 2017 Office Action Response at 5-8 • April 20, 2017 Office Action Response at 5-9 • September 9, 2016 Office Action Response at 5-9 	Stevenson and Lindeberg, Oxford University Press, Inc., 2010 (“sequence”) at 1593 Plaintiffs’ Responses to Invalidity Contentions. Plaintiffs’ Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties’ extrinsic evidence.
“canister fire configuration”	’156 Patent: 1, 2	“configuration in which the [actuator pawl as construed by Defendants] is lower than in the [first reset position as construed by Defendants] and below the [datum plane as	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 13:40-15:32 • Figs. 10A-10F 	<u>Extrinsic Evidence:</u> Plaintiffs’ Responses to Invalidity Contentions.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
		construed by Defendants] and the medicament is ejected"	<p>'156 Patent File History generally including but not limited to:</p> <ul style="list-style-type: none"> • August 22, 2017 Office Action Response at 5-8 • April 20, 2017 Office Action Response at 5-9 • September 9, 2016 Office Action Response at 5-9 	<p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"count configuration"	'156 Patent: 1	"configuration in which the [actuator pawl as construed by Defendants] is further below the [datum plane as construed by Defendants] than when in the [canister fire position as construed by Defendants] and the dose counter has counted one dose"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 13:40-15:32 • Figs. 10A-10F <p>'156 Patent File History generally including but not limited to:</p> <ul style="list-style-type: none"> • August 22, 2017 Office Action Response at 5-8 • April 20, 2017 Office Action Response at 5-9 • September 9, 2016 Office Action Response at 5-9 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				intrinsic evidence, and the parties' extrinsic evidence.
"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"	'156 Patent: 1	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 1:41-48 • 12:23-29 • 13:40-15:32 • Fig. 3A • Fig. 9 <p>'156 Patent File History generally including but not limited to:</p> <ul style="list-style-type: none"> • May 31, 2018 Notice of Allowance • March 13, 2018 Office Action Response at 6-7 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"the body"	'156 Patent: 12	This term is indefinite.	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • Claim 12 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"wall surfaces separating the canister-receiving portion and the counter chamber"	'156 Patent: 12 '512 Patent: 2, 3	"wall extending inwardly from the interior surface of the canister housing and separating a canister-receiving portion from the [dose counter chamber as construed by Defendants]"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> • 12:38-53 • Figs. 7B-7D 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"separate counter chamber" / "dose counter chamber"	'156 Patent: 12 '512 Patent: 2, 3	"enclosed space or cavity containing the dose counter separated from the canister-receiving portion" / "enclosed space or cavity containing the dose counter"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> 12:38-53 Figs. 7B-7D 	<u>Extrinsic Evidence:</u> New Oxford American Dictionary, 3 rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("chamber") at 287. Plaintiffs' Responses to Invalidity Contentions. Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"counter display arranged to indicate dosage information"	'808 Patent: 1	"structure displaying the total number of doses remaining in a medicament canister"	<u>Intrinsic Evidence:</u> Patents-in-Suit generally, including but not limited to: <ul style="list-style-type: none"> 13:14-16 	<u>Extrinsic Evidence:</u> Plaintiffs' Responses to Invalidity Contentions.

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
			<ul style="list-style-type: none"> 17:7-10 21:1-4 	<p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"first direction"	'808 Patent: 1	"single direction"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> 2:65-67 3:47-56 5:35-38 8:54-67 13:10-22 16:28-53 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				intrinsic evidence, and the parties' extrinsic evidence.
"first station"	'808 Patent: 1	"first structure on which the [counter display as construed by Defendants] is located"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 2:65-67 • 3:47-56 • 5:35-38 • 8:54-67 • 13:10-22 • 16:28-53 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"second station"	'808 Patent: 1	"second structure, separate from the first structure, to which the [counter display as construed by Defendants] is moved"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 2:65-67 • 3:47-56 • 5:35-38 • 8:54-67 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
			<ul style="list-style-type: none"> 13:10-22 16:28-53 	<p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"regulator"	'808 Patent: 1, 27	"structure configured to prevent unwanted movement"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> 2:51-53 3:3-7 4:39-45 19:1-20:13 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				intrinsic evidence, and the parties' extrinsic evidence.
"regulate motion of the counter display"	'808 Patent: 1	"prevent unwanted movement of the counter display"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 2:51-53 • 3:3-7 • 4:39-45 • 19:1-20:13 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"chassis"	'512 Patent: 1	"supporting frame or structure having a first shaft and second shaft"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 13:3-9 • Fig. 4A • Figs. 6A-6G 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"pins"	'512 Patent: 1	"small shafts"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> Figs. 8A-8B 	<p><u>Extrinsic Evidence:</u></p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
"a pin or aperture heat staked to a respective aperture or pin"	'512 Patent: 1	"a [pin as construed by Defendants] and [aperture as construed by Defendants] joined together using heat to deform the [pin as construed by Defendants]"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 7:61-8:4 • 8:12-18 • 16:54-66 <p>U.S. Patent No. 9,533,111 File History generally, including but not limited to:</p> <ul style="list-style-type: none"> • July 12, 2016 Office Action at 2-4 • September 28, 2016 Office Action Response at 3-4 • October 13, 2016 Notice of Allowance 	<p><u>Extrinsic Evidence:</u></p> <p>U.S. Patent Application No. 2012/0006322.</p> <p>Plastics Engineering Handbook, 4th Edition, Frados, Joel, Van Nostrand Reihold Co., 1976 at 808-809.</p> <p>Decoration and Assembly of Plastic Parts, Edward A. Muccio, ASM International, 1999 at 100-109.</p> <p>Plastic Part Technology, Edward A Muccio, ASM International, 1991 at 266.</p> <p>Handbook of Plastics Joining, 2nd Edition, Michael J. Troughton, William Andrew Inc., 2008 at 195-200.</p> <p>U.S. Patent No. 6,296,470.</p> <p>U.S. Patent No. 5,095,606.</p> <p>U.S. Patent No. 4,767,298.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				<p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"different sides"	'512 Patent: 1	"distinct surfaces where each the pin/aperture of the chassis connects to a different face of the body"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • Figs. 6A-6B • Figs. 8A-8C <p>'512 Patent File History generally, including but not limited to:</p> <ul style="list-style-type: none"> • February 24, 2020 Notice of Allowance 	<p><u>Extrinsic Evidence:</u></p> <p>U.S. Patent Application No. 2012/0006322</p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
			<p>U.S. Patent No. 9,533,111 File History generally, including but not limited to:</p> <ul style="list-style-type: none"> July 12, 2016 Office Action September 28, 2016 Office Action Response October 13, 2016 Notice of Allowance 	<p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.</p>
"formed in the body"	'512 Patent: 2	"a unified part of the body"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> 12:39-53 Figs. 7C, 7D 	<p><u>Extrinsic Evidence:</u></p> <p>New Oxford American Dictionary, 3rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("in") at 875-76</p> <p>New Oxford American Dictionary, 3rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("formed") at 680-81.</p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.
"fixed to the body"	'512 Patent: 3	"attached to the body and not readily removable"	<p><u>Intrinsic Evidence:</u></p> <p>Patents-in-Suit generally, including but not limited to:</p> <ul style="list-style-type: none"> • 8:23-27 • 16:66-17:3 • Figs. 8A-8D 	<p><u>Extrinsic Evidence:</u></p> <p>New Oxford American Dictionary, 3rd Edition, Stevenson and Lindeberg, Oxford University Press, Inc., 2010 ("fixed") at 655.</p> <p>Plaintiffs' Responses to Invalidity Contentions.</p> <p>Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions.</p> <p>Expert opinions and/or testimony regarding how a person of ordinary skill in the art would understand the meaning of this term based</p>

Claim Term	Asserted Claims Reciting Term	Defendants' Proposed Construction	Defendants' Evidence ²	
				on the disclosures in the patent specification, other intrinsic evidence, and the parties' extrinsic evidence.

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Peter Toller

EXHIBIT 12

Dictionary of Mechanical Engineering

Fourth Edition

G.H.F. Nayler

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Preface to First Edition

This dictionary has been compiled to cover the very large number of mechanical engineering terms in common use in a handy compact volume. The term “mechanical engineering” has been interpreted as mainly the production of, the means for, and the utilization of, mechanical power in engines, transport and mechanisms. It has also been borne in mind that tools, and the making of them, are of first importance, but in order to keep within certain limits those tools that are used by hand have been omitted, except for one or two rare exceptions.

As regards power, its production involves the design and construction of many types of device to enable energy to be developed from fundamental sources and then on to prime movers. As far as possible, terms likely to be found in other dictionaries of the series have been omitted, except where the application of a term is clearly common to more than one branch of engineering. Consequently, many fields allied to the mechanical engineering industry, such as foundry practice, metallurgy, metrology and welding, all of which are vital to the industry but are not in themselves mechanical, have been given only minor attention.

In preparing a work of this kind it is necessary to consult many sources, since the choice of clear and concise definitions is always a difficult task. The selection of terms has been based mainly on the reading of current literature, including the foremost engineering journals. Thus many well known but little used terms may not be found. Terms printed in bold italics in the text indicate entries that will provide the reader with additional information.

The illustrations are intended to help the less expert and are spread over the large field of mechanical engineering, while avoiding intricate subjects which are too complicated for simple line drawings.

The authors are much indebted to Miss E. E. Metcalfe for her valuable assistance in the preparation of the line drawings, and to the Publishers' staff* for their helpful cooperation at all times during the passage of the dictionary through the press.

J.L. and G.H.F. Naylor

*George Newnes Ltd., London

Preface to Fourth Edition

The dictionary has been further updated and enlarged while retaining practically all of its original contents. With the recent advances in very small size mechanical engineering, micromachining and nanotechnology have been included. Nomenclature used in the manufacture of composites has also been added. Terms which have their main usage on the North American Continent now receive more prominence than previously. Cross-references have always been given full and careful attention and, where relevant, the reader is guided, as in a thesaurus, to a term of opposite meaning.

Clear understandable terminology is essential to efficient, accurate and comprehensive information distribution and retrieval. It is hoped that this edition will further the above aims worldwide in the field of mechanical engineering.

Acknowledgments

I am pleased to record my gratitude to Don Goodsell for his advice and encouragement and for the use of four figures from his companion *Dictionary of Automotive Engineering*. I am also grateful to the staff of the Society of Automotive Engineers for their full support in the production of this edition, and Butterworth-Heinemann for co-publishing this work.

Gordon H.F. Naylor

shimmy damper A damper for the suppression of *shimmy*.

torsional vibration damper A flywheel mounted on a shaft with the relative motion damped by viscous friction.

tuned torsional vibration damper A flywheel coupled to a shaft by a spring to form a resonant system effective at frequencies near its natural frequency. See also *detuner*; *shock absorber*.

vibration dampers **Dampers** fitted to an engine crankshaft to suppress or reduce stresses resulting from torsional vibration at critical running speeds.

damping The process by which the energy of a vibrating system is dissipated.

coulomb damping Damping in which the force opposing a motion has a constant magnitude.

critical damping coefficient The smallest value of the damping coefficient required to prevent vibration.

damping coefficient The constant coefficient of the velocity term, \dot{x} , in a motion defined by the differential equation $m\ddot{x} + c\dot{x} + kx = 0$, where m is the mass and k is the stiffness of the system.

damping factor See *decay factor*.

damping ratio The ratio of the *damping coefficient* to the *critical damping coefficient*.

internal damping Damping intrinsic to the materials.

magnetic damping Damping due to eddy currents set up by the movement of a system in a magnetic field.

nonlinear damping Damping derived from a damping force which is not proportional to velocity.

structural damping Damping due to the total effect of a built-up structure.

viscous damping Damping in which the opposing force is proportional to the velocity.

damping slipper A device restricting lateral *thrash* of a *belt* or *chain* especially a *timing chain*.

dashpot (a) A damping device consisting of a piston and cylinder whose relative motion is opposed by the fluid friction of a liquid or of air. It provides forces proportional to the rate of movement of the piston when a spring is added to the device. A one-way valve may be incorporated to give a differential damping action. (See *air dashpot* and *Figure A.3*.) (b) A cylinder employed in steam engines fitted with trip gears for closing the admission valves suddenly as soon as they are released by the trip.

datum (a) A point from which all measurements are made. (b) A line from which all measurements are made. (c) A horizontal plane from which all vertical measurements are made. See *datum line*; *datum plane*; *datum point*.

datum dimension See *dimension*.

datum feature See *feature*.

datum level A base line of a section from which all heights and depths are measured.

datum line A defined line or base from which dimensions are taken or calculations are made. It establishes an exact geometrical reference.

datum plane (a) A plane occupying a defined position from which dimensions are taken or calculations are made. It establishes an exact geometrical reference. (b) That plane of a *rack* in which the ratio of tooth thickness to pitch has a specified value, normally 0.5.

datum point (a) A point occupying a defined position from which dimensions are taken or calculations are made. It establishes an exact geometrical reference. (b) The fixed starting point of a scale.

D-bit See *cylinder bit*.

davits Curved or F-shaped uprights fitted with tackle for raising, lowering or suspending a boat.

daylight (a) The mismatch between two adjacent items. (b) In a machine press, the distance between *bed* and the lowest position of the face of the *ram*.

De Dion axle A motor vehicle rear suspension, the final differential drive of which is bolted to the frame of the vehicle. The *cardan shaft* stub-axles are driven through *universal joints* adjacent to the final differential drive and to the wheels which are supported by leaf springs from the vehicle frame. See *pot joint* and *Figure D.1*.

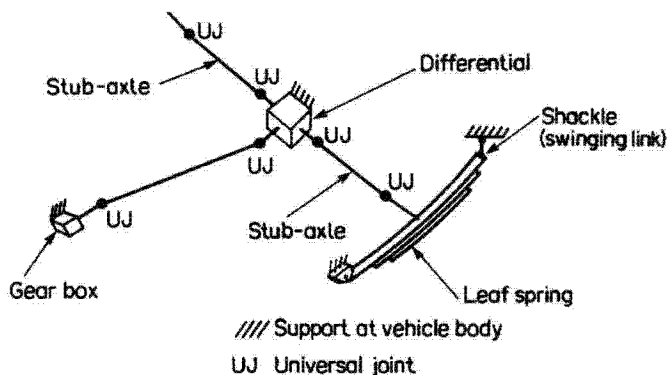


Figure D.1 De Dion axle.

De Laval turbine An early single-wheel *impulse turbine*.

de-clutch Disengagement of a *clutch*.

dead angle The angle of movement of the crank of a steam engine during which the engine will not start when the *stop valve* is opened due to the ports being closed by the *slide valve*.

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Christine A. Lindberg

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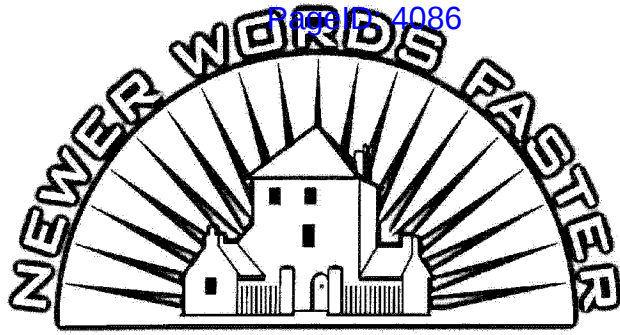
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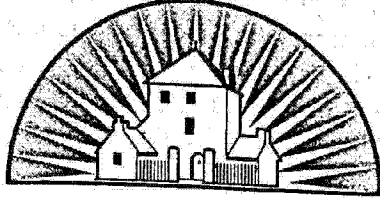


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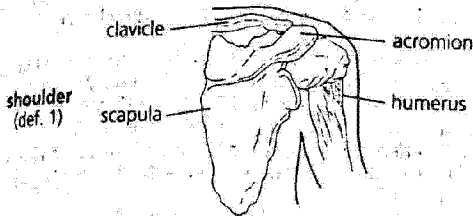
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1197
[The shoulder, OE *sc(e)olde*; see *SHALL*] —Usage. Rules similar to those for choosing between *shall* and *will* have long been advanced for *should* and *would*, but most educated native speakers of American English do not follow the textbooks. In most constructions, *would* is the auxiliary chosen regardless of the subject: *If our allies supported the move, we would abandon any claim to sovereignty*. Because the main function of *should* in modern American English is to express necessity, etc., its use for other purposes, as to form a subjunctive, can produce ambiguity, at least initially: *I should get my flu shot if I were you*. Furthermore, *should* seems an affectation to many Americans in certain constructions quite common to British English: *I should (American would) really prefer a different arrangement*. See also *SHALL*.

shoulder (shōl'dər), *n.* 1. the part on either side of the human body where the arm joins with the trunk, extending from the base of the neck to the upper arm. 2. *Usu., shoulders*, these two parts together with the part of the back joining them. 3. a corresponding part in animals. 4. the upper foreleg and adjoining parts of a sheep, goat, etc. 5. the part of a garment that fits over the shoulder. 6. a shoulderlike part or projection. 7. a cut of meat that includes the upper joint of the foreleg. 8. *Often, shoulders*, capacity for bearing responsibility or blame. *The duty rests on our shoulders*. 9. a steplike change in the contour of an object. 10. the flat surface on a type body extending beyond the base of the letter or character. 11. a border alongside a roadway. —*v.t.* 12. to push with or as if with the shoulder. 13. to support or carry on the shoulder or shoulders: *to shoulder a knapsack*. 14. to assume as a responsibility: *We shouldered the expense*. —*v.i.* 15. to push with or as if with the shoulder: *shouldering through a crowd*. —*Idiom*. 16. **shoulder to shoulder**, side by side; with united effort. [bef. 900; ME *sholder*, *s(c)hulder*, OE *sculdor*, c. OFris *skuldere*, OHG *sculter(r)a*]



shoulder bag, *n.* a handbag with a shoulder strap. [1940–45]

shoulder blade, *n.* SCAPULA. [1250–1300]

shoulder board, *n.* either of a pair of stiffened epaulets worn on the shoulders of a military officer's uniform. [1940–45]

shoulder knot, *n.* 1. a knot of ribbon or lace worn on the shoulder in the 17th and 18th centuries. 2. a military ornament of braided cord worn on the shoulders on ceremonial occasions. [1670–80]

shoulder patch, *n.* a cloth identifying emblem worn on the upper sleeve of a uniform. [1940–45]

shoulder strap, *n.* a strap passing over the shoulder and supporting a garment or article. [1680–90]

shouldn't (shōd'nt), contraction of *should not*.

shouldst (shōdst, shōdst) also **should'est** (shōd'ist), *v.* Archaic. 2nd pers. sing. past of *SHALL*.

shout (shout), *v.i.* 1. to call or cry out loudly. —*v.t.* 2. to utter loudly. —*n.* 3. a loud call or cry: *a shout for help*. [1300–50; ME *shoute* (*n.*), *shouten* (*v.*)] —**shout'er**, *n.*

shouting distance, *n.* HAILING DISTANCE. [1950–55]

shove (shuv), *v.*, **shoved**, **shoving**, *n.* —*v.t.* 1. to propel along. 2. to push roughly or rudely; jostle. —*v.i.* 3. to push. 4. **shove off**, *a.* to push a boat from the shore. *b.* to go away; depart. —*n.* 5. an act or instance of shoving. [bef. 900; (v.) ME *schouven*, OE *scūfan*, c. OFris *skūfa*, ON *skúfa*] —**shov'er**, *n.*

shovel (shuv'əl), *n.*, *v.*, —**eled**, —**eling** or (esp. Brit.) —**elled**, —**eling**. 1. a hand implement consisting of a broad blade or scoop attached to a long handle, used for taking up or throwing loose matter. 2. any fairly large contrivance or machine with a broad blade having a similar purpose: *a steam shovel*. —*v.t.* 3. to take up and cast with a shovel: *to shovel coal*. 4. to gather up in large quantity energetically with or as if with a shovel: *to shovel food into one's mouth*. 5. to dig or clear with or as if with a shovel. —*v.i.* 6. to use a shovel. [bef. 900; ME *OE scoff*, c. MD, D *schoffel*; akin to OHG *scūvala*, *shove*]

shoveler (shuv'ə-lər, shuv'lər), *n.* 1. a person or thing that shovels. 2. a freshwater duck of the Northern Hemisphere, *Anas clypeata*, having a broad, flat bill. [1400–50]

shovel hat, *n.* a hat with a shallow crown and a broad brim turned up at the sides, worn esp. by some clergymen. [1825–35]

shovel-nosed, *adj.* having the head, snout, or beak broad and flat like the blade of a shovel. [1700–10]

show (shō), *v.*, **showed**, **shown** or **showed**, **showing**, *n.* —*v.t.* 1. to cause or allow to be seen; exhibit; display. 2. to present or perform as a public entertainment or spectacle: *to show a movie*. 3. to indicate; point out: *to show the way*. 4. to guide; escort: *Show her in*. 5. to make known; explain: *He showed what he meant*. 6. to reveal; demonstrate: *Your work shows promise*. 7. to register; mark: *The thermometer showed 10 below zero*. 8. to exhibit or offer for sale: *to show a house*. 9. to allege, as in a legal document: *to show cause*. 10. to produce, as facts in an affidavit or at a hearing. 11. to offer; grant: *to show mercy*. —*v.i.* 12. to be or become visible: *Does my slip show?* 13.

to be manifested in a certain way: *to show to advantage*. 14. to put on an exhibition or performance: *Several designers are showing now*. 15. to make an appearance; show up. 16. to finish third, as in a horse race. 17. **show off**, *a.* to display to advantage: *The gold frame shows off the picture beautifully*. *b.* to present for admiration or approval: *young parents showing off their new baby*. *c.* to seek attention by ostentatious or insistent display of one's talent, possessions, achievements, etc. 18. **show up**, *a.* to make known; reveal: *It showed up the flaws in the plan*. *b.* to appear as specified; be seen: *White shows up well against the blue*. *c.* to come to or arrive at a place. *d.* to make (another) seem inferior; outdo. —*n.* 19. a theatrical production, performance, or company. 20. a radio or television program. 21. a motion picture. 22. an exposition of products by various manufacturers in a particular industry. 23. exhibition: *a show of Renoirs*. 24. ostentatious display: *all show and no substance*. 25. a display or demonstration: *a show of courage*. 26. the position of the competitor who comes in third, as in a horse race. Compare *PLACE* (def. 24b), *WIN* (def. 15). 27. appearance; impression: *to make a sorry show*. 28. a sight or spectacle. 29. *a.* the first appearance of blood at the onset of menstruation. *b.* a blood-tinged mucous discharge from the vagina that indicates the onset of labor. [bef. 900; ME *shopen*, *s(c)hewen*, to look at, show, OE *scēawan* to look at]

show/ and tell, *n.* 1. a classroom activity for young children in which each child produces an object and talks about it. 2. any informative presentation or demonstration. [1950–55]

show/ bill, *n.* an advertising poster. [1795–1805]

show/ biz, *n.* Informal. SHOW BUSINESS. [1945–50]

show-boat (shō'bōt'), *n.* 1. a boat, esp. a paddle-wheel steamer, used as a traveling theater. 2. a show-off. —*v.i.* 3. to perform or behave flamboyantly. [1865–70, Amer.]

show-bread (shō'bred'), *n.* SHEWBREAD.

show/ busi/ness, *n.* the entertainment industry, as theater, motion pictures, television, radio, carnival, and circus. [1925–30]

show-case (shō'kās'), *n.*, *v.*, —**cased**, —**cas-ing**. —*n.* 1. a glass case for the display and protection of articles. 2. an exhibit or display, usu. of an ideal or representative model of something. 3. the setting, place, or vehicle for displaying something on a trial basis: *The club is a show-case for new comics*. —*v.t.* 4. to exhibit or display. 5. to present in or as if in an entertainment showcase. 6. to present as a special event: *The TV network plans to showcase the play*. [1830–40]

show-down (shō'daun'), *n.* 1. (esp. in poker) the laying down of all the players' cards faceup to determine the winner in a hand. 2. a conclusive confrontation or settlement. [1880–85, Amer.]

show-er (shō'ər), *n.* 1. a brief fall of rain or of hail or snow. 2. Also called **show'er bath**, a bath in which water is sprayed on the body from above. 3. the apparatus or space for providing such a bath. 4. something resembling a shower: *a shower of sparks*. 5. a party given to bestow presents of a specific kind upon the honoree. —*v.t.* 6. to bestow liberally or lavishly. 7. to give to in abundance: *showered with praise*. 8. to bathe (oneself) in a shower. —*v.i.* 9. to rain in a shower. 10. to bathe in a shower. [bef. 950; ME *shour*, OE *scūr*, c. OS, ON *skūr*, OHG *scūr*, Go *skūra*] —**show'er-y**, *adj.*

show-ing (shō'ing), *n.* 1. display; exhibition. 2. the act of putting something on display. 3. a performance or record considered for the impression it makes: *made a good showing at the polls*. 4. a setting forth or presentation, as of facts or conditions. [bef. 950]

show-man (shō'man), *n.*, *pl.* —**men**. 1. a person who produces theatrical works. 2. a person gifted in dramatic presentation. [1725–35] —**show/man-ly**, *adv.* —**show/man-ship**, *n.*

shown (shōn), *v.* a pp. of *SHOW*.

show/-off, *n.* 1. a person given to pretentious display. 2. the act of showing off. [1770–80] —**show/-off-ish**, *adj.*

show-piece (shō'pēs'), *n.* something exhibited or worthy of exhibiting as a fine example of its kind. [1880–85]

show-place (shō'plās'), *n.* a place, as an estate or mansion, notable for its beauty, historical interest, etc. [1570–80]

show-room (shō'rōom', -rōom'), *n.* a room used for the display of goods or merchandise. [1610–20]

show/-stop/per, *n.* a performer or performance that wins enthusiastic or prolonged applause. [1945–50] —**show/-stop/ping**, *adj.*

show/ tri/al, *n.* the public trial of a political offender conducted chiefly for propagandist purposes. [1945–50]

show/ win/dow, *n.* a display window in a store. [1830–40, Amer.]

show-y (shō'yē), *adj.*, **show-i-er**, **show-i-est**. 1. making an imposing display: *showy flowers*. 2. pompous; ostentatious; gaudy. [1705–15] —**show/i-ly**, *adv.* —**show/i-ness**, *n.*

sho-yu (shō'yōō), *n.* SOY SAUCE. [1725–30; < Japn *shōyu*]

shrank (shrangk), *v.* a pt. of *SHRINK*.

shrap-nel (shrap'nl), *n.* 1. fragments scattered by a bursting artillery shell, mine, or bomb. 2. a hollow projectile of the 19th century containing bullets and a bursting charge, designed to explode in the air and shower the target with missiles. [1800–10; after Henry Shrapnel (1761–1842), English army officer, its inventor]

shred (shred), *n.*, **shred-ded** or **shred**, **shred-ding**. —*n.* 1. a piece cut or torn off, esp. in a narrow strip. 2. a bit; scrap: *not a shred of evidence*. —*v.t.* 3. to cut or tear into small pieces. —*v.i.* 4. to fragment into shreds. [bef. 1000; ME *schrede*, OE *scrēde*, c. OFris *skrēd* clipping, OS *skrōd*, OHG *scrōt*; akin to *SHROUD*]

shred-der (shred'ər), *n.* 1. a person or thing that shreds. 2. a machine for shredding documents. [1565–75]

Shreve-port (shrev'pōrt', -pōrt'), *n.* a city in NW Louisiana, on the Red River. 218,010.

EXHIBIT 15

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EXHIBIT 16

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sale of securities or commodities which the seller does not expect to cover later at a lower price

short story a brief time granted a condemned person for confession and absolution before his execution 2 very care or attention, as from lack of patience or sympathy — **short shift** of to make short work of; dispose of quickly and

short-sighted (-sīt'id) *adj.* 1 NEARSIGHTED 2 having or showing a lack of foresight — **short-sight'edly** *adv.* — **short-sight'ed-ness** *n.*

short snort (Slang) a quick drink of liquor

short-spoken (-spōk'an) *adj.* 1 using only a few words; laconic 2 to the point of rudeness; curt

short stop (-stap') *n.* Baseball 1 the infielder who plays on the left side of the infield near second base and often covers second base 2 a defensive position played by this infielder

short story a kind of story shorter than the novel or novelette, characteristically developing a single central theme and limited in scope and number of characters

short subject a film short, as that shown with a film feature

short-tempered (-tem'pərd) *adj.* having a tendency to lose one's temper, easily or quickly angered

short-term (-tərm') *adj.* 1 for or extending over a short time 2 designating or of a capital gain, loan, etc. that involves a relatively short period, usually of less than a year

short-ton see TON (sense 1): abbrev. *st*

short-waisted (-wāst'id) *adj.* unusually short between shoulders and waistline; with a high waistline

short-wave (-wāv') *n.* 1 an electromagnetic wave that is shorter than those used in commercial broadcasting, usually a radio wave of meters or less in length 2 a radio or radio band for broadcast or receiving shortwaves: in full **shortwave radio** 3 a) the band of frequencies (approximately 1.7 to 30 megahertz) used for short-wave transmissions by international broadcasters, licensed amateurs and other operators b) the transmissions that are broadcast

short-winded (-win'did) *adj.* 1 easily put out of breath by exertion 2 breathing with quick, labored breaths 3 brief, often overly and undesirably so: said of speech or writing

shorty (-ē) *n. pl.* **short-ies** [Informal] a person or thing of less than average height or size

Shoshone (shō shō'nē) *n.* 1 *Shoshonean* *tsosoni*, curly head, in allusion to their hairdo 1 *pl.* --nes or -ne a member of a group of North American Indians scattered over Idaho, Nevada, Utah, Wyoming, and California 2 the Shoshonean language of this people

Sho-sho'ni

Shoshone (shō shō'nē) river in NW Wyo., flowing northeast into the Bighorn River: c. 100 mi (161 km)

Sho-sho-nean (shō shō'nē ən, shō'shə nē'ən) *adj.* designating or of a branch of the Uto-Aztecan language family, including Shoshone, Comanche, Ute, Paiute, and Hopi — *n.* this branch of the Uto-Aztecan language family

Shoshone Falls waterfall on the Snake River, in S Ida.: c. 200 ft (61 m)

Shostakovich (shō'stā kō'vich; E shās'tə kō'vich), Dmi'tri (d'mē'tri) 1906-75; Russ. composer

shot (shāt) *n.* [ME < OE *sceot* < *sceotan* (akin to ON *skot*, Ger *schossen*; see SHOOT)] 1 the act of shooting; discharge of a missile, esp. from a gun 2 a) the distance over which a missile travels b) range; reach; scope 3 an attempt to hit with a missile 4 a) any attempt or try b) a guess or conjecture 5 a pointed, critical remark 6 a) in various games, the flight or path of a ball, puck, etc. after it is shot toward a goal or other object b) a stroke, as in tennis or golf c) an attempt to score, as in basketball or hockey 7 a solid projectile designed for discharge from a firearm or cannon, as distinguished from an explosive shell b) such projectiles collectively 8 a) lead or steel in small pellets, of which a quantity is used for a single charge of a shotgun b) a single pellet of this kind 9 the heavy metal ball used in the SHOT PUT 10 a blast, or the amount of explosive used for a blast, as in mining 11 a marksmanship 12 a) the act of taking a single photograph b) a single photograph c) a single, continuous image as taken on film, by a camera, or by a live TV camera 13 [cf. SCOT] an amount due, esp. for drinks or entertainment 14 a hypodermic injection, as of vaccine 15 a drink of liquor; specif., JIGGER 16 [Informal] something to bet on, considered from the standpoint of odds or chances 17 a) a horse that is a ten-to-one shot 17 Naut. a 90-foot length of chain, esp. for an anchor — *vt.* **shot'ted**, **shot'ting** to beat or weight with shot — *a shot in the arm* something that bolsters up, reinvigorates, encourages, etc., esp. in a difficult situation — *call the shots* [Informal] 1 to give orders 2 to control what is done or what happens — *have (or take) a shot at* [Informal] to try to do or win — *like a shot* 1 quickly; rapidly 2 suddenly

shot (shāt) *vt., vi. pt. & pp. of SHOOT* — *adj.* 1 variegated, streaked, flecked, etc. with another color or substance 2 woven with threads of different colors so as to appear iridescent 3 varied or something different [a novel shot through with pathos] 4 [Informal] ruined or worn out

shot clock Basketball a timing device that indicates the number of seconds a team has in which to attempt a shot or else lose possession of the ball

shotgun (shāt'gun') *n.* 1 a smoothbore gun, usually used for firing a charge of shot at short range, as in hunting small game 2 an offensive formation, esp. for passing, in which the quarterback takes the snap while standing several yards behind

the line of scrimmage: often **shotgun formation** — *vt., vi.* to shoot, force, or threaten with a shotgun — *adj.* 1 done or made under duress 2 with no fixed direction or target 3 designating a long, narrow house, apartment, etc. with rooms arranged one behind the other — **ride shotgun** 1 [Historical] in the W U.S., to go along as an armed guard, esp. with the driver of a stagecoach 2 to accompany for protection, as in the front seat of a motor vehicle

shotgun wedding a wedding into which one or both partners are forced, as because of previous sexual intimacy or, esp., pregnancy

shot hole 1 a drilled hole in which an explosive charge is put for blasting 2 a hole bored in timber by an insect

shot put *Track & Field* 1 a contest in which a heavy metal ball is propelled for distance with an overhand thrust from the shoulder 2 a single put of the shot — **shot-put'ter** *n.* — **shot-put'ting** *n.*

shott (shāt) *n.* [Fr *chott* < Ar *shatt*, orig., river bank] in N Africa, a closed basin, often containing a temporary, shallow, brackish lake

shot-ten (shāt'n) *vt., vi. obs. pp. of SHOOT* — *adj.* [in specialized sense (esp. applied to herrings), prob. infl. by Du *schoten*] 1 that has recently spawned and so become of inferior food value: said of fish 2 [Archaic] undesirable

should (shood) *v. aux.* [ME *scholde* < OE *sceolde*, pt. of *sceal*, *scal*, I am obliged: see SHALL] 1 *pt. of SHALL* [I had hoped I should see you] 2 used to express obligation, duty, propriety, or desirability [you should ask first, the plants should be watered weekly] 3 used to express expectation or probability [he should be here soon, I should know by tomorrow] 4 used to express a future condition [if I should die tomorrow, if you should be late] 5 used in polite or tentative expression of opinion [I should think they will be pleased] See usage note at WILL

shoulder (shōl'dar) *n.* [ME *schuldere* < OE *sculdor*, akin to Ger *schulter* < IE **skl'dhrā*, shoulder blade used as a spade < base **skel-*, to cut > SHELL, SHILLING, SKULL] 1 a) the joint connecting the arm or forelimb with the body b) the part of the body including this joint and extending to the base of the neck 2 *pl.* the two shoulders and the part of the back between them: often used figuratively with reference to this region as a place where burdens are often carried 3 a cut of meat consisting of the upper foreleg and attached parts: see PORK, illus. 4 the part of a garment that covers the shoulder 5 something like a shoulder in shape or position; shoulderlike projection 6 that part of the top of a piece of type which extends beyond the base of the raised character: see TYPE, illus. 7 the strip of land along the edge of a paved road; berm — *vt.* 1 to push or thrust along or through, with or as with the shoulder (to shoulder one's way through a crowd) 2 to take or carry upon the shoulder 3 to assume the burden of — *vi.* to push with the shoulder or shoulders — **cry on someone's shoulder** to tell one's troubles to someone in seeking comfort or sympathy — **put one's shoulder to the wheel** to set to work vigorously; put forth vigorous effort — **shoulder arms** *Mil.* 1 to rest a rifle against the (right or left) shoulder, supporting the butt with the hand on the same side 2 a) this position b) the command to assume it — **shoulder to shoulder** 1 side by side and close together 2 working together; with common effort — **straight from the shoulder** 1 moving straight forward from the shoulder: said of a blow 2 without reserve or evasion; frankly — **turn (or give) a cold shoulder to** 1 to treat with disdain; snub 2 to avoid or shun

shoulder bag a bag of leather, cloth, etc. hung from the shoulder by a long strap, as for carrying personal effects

shoulder blade SCAPULA

shoulder board (or **mark**) either of a pair of oblong pieces of stiffened cloth worn on the shoulders of certain uniforms and showing insignia of rank

shoulder girdle PECTORAL GIRDLE

shoulder harness a restraining device consisting of an anchored strap passing diagonally across the chest, used with a seat belt, as in an automobile: also called **shoulder belt**

shoulder holster a holster attached to a shoulder strap and usually worn under the arm, allowing a handgun to be concealed beneath a jacket or coat

shoulder knot 1 a knot of ribbon or lace formerly worn as an ornament on the shoulder 2 a detachable ornament of braided cord worn on the shoulders of full-dress uniforms

shoulder patch a cloth insignia identifying the wearer's unit, branch of service, etc., worn on the sleeve of a uniform, just below the shoulder

shoulder strap 1 a strap, usually one of a pair, worn over the shoulder to support a garment 2 a strap worn over the shoulder for carrying a purse, camera, etc.

shouldn't (shood'nt, shoont) contraction should not

shooldst (shoodst) *v. archaic* 2d pers. sing. pt. of SHALL: used with *thou*: also **should'est** (shood'ist)

should've (shood'ev) contraction should have

shout (shout) *n.* [ME *schoute*, prob. < an OE cognate of ON *skūta*, a taunt, prob. < IE **skud-*, to cry out > SCOUT] 1 a loud cry or call 2 any sudden, loud outburst or uproar 3 [orig. uncert.] [Austral. & N.Z. Informal] one's turn to buy a round of drinks, etc. — *vt.* 1 to utter or express in a shout 2 [Austral. & N.Z. Informal] to treat (someone) to (a round of drinks, etc.) — *vi.* to utter a shout; cry out loudly — **shout down** to silence or overwhelm by loud shouting; shout louder than — **shout'er** *n.*

shove (shuv) *vt., vi.* shoved, **shov'ing** [ME *shoven* < OE *scufan*, akin to ON *skufa*, Ger *schieben* < IE base **skeubh-*, to throw, shove

See the inside front cover for pronunciation information.
The symbol * is used to mark terms of American origin.

EXHIBIT 17

(12) **United States Patent**
Castro et al.

(10) **Patent No.: US 6,640,805 B2**
 (45) **Date of Patent: Nov. 4, 2003**

(54) **METERING VALVE FOR A METERED DOSE INHALER HAVING IMPROVED FLOW**

(75) Inventors: **Gustavo H. Castro**, Cottage Grove, MN (US); **Thomas Herdtle**, Inver Grove Heights, MN (US); **Cathleen M. Arsenault**, Hugo, MN (US); **Antony J. Davis**, Hugglescote (GB)

(73) Assignee: **3M Innovative Properties Company**, St. Paul, MN (US)

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(52) **U.S. Cl.** **128/200.23**; 128/200.14; 222/1; 222/394; 222/402.1

(58) **Field of Search** 128/200.23, 200.13, 128/200.14; 222/402.1, 394, 372, 402.19, 402.16, 402.2

(56) **References Cited**

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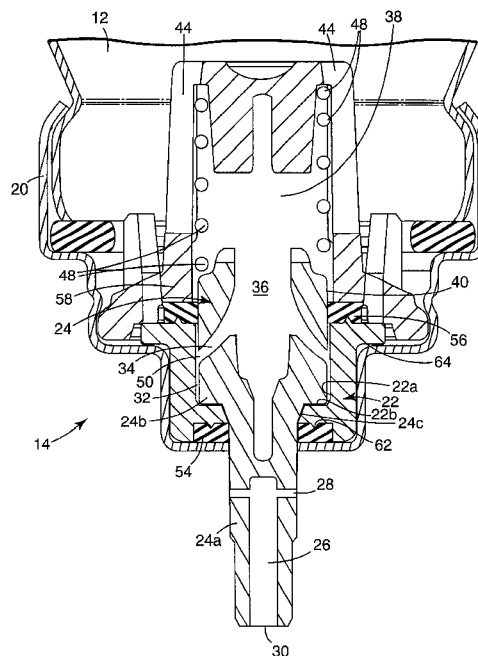
Assistant Examiner—Michael G. Mendoza

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(57) **ABSTRACT**

A novel metering valve having improved flow for delivery of an aerosol formulation is disclosed. Methods of delivering an aerosol formulation using a device comprising the novel metering valve are also disclosed.

30 Claims, 10 Drawing Sheets



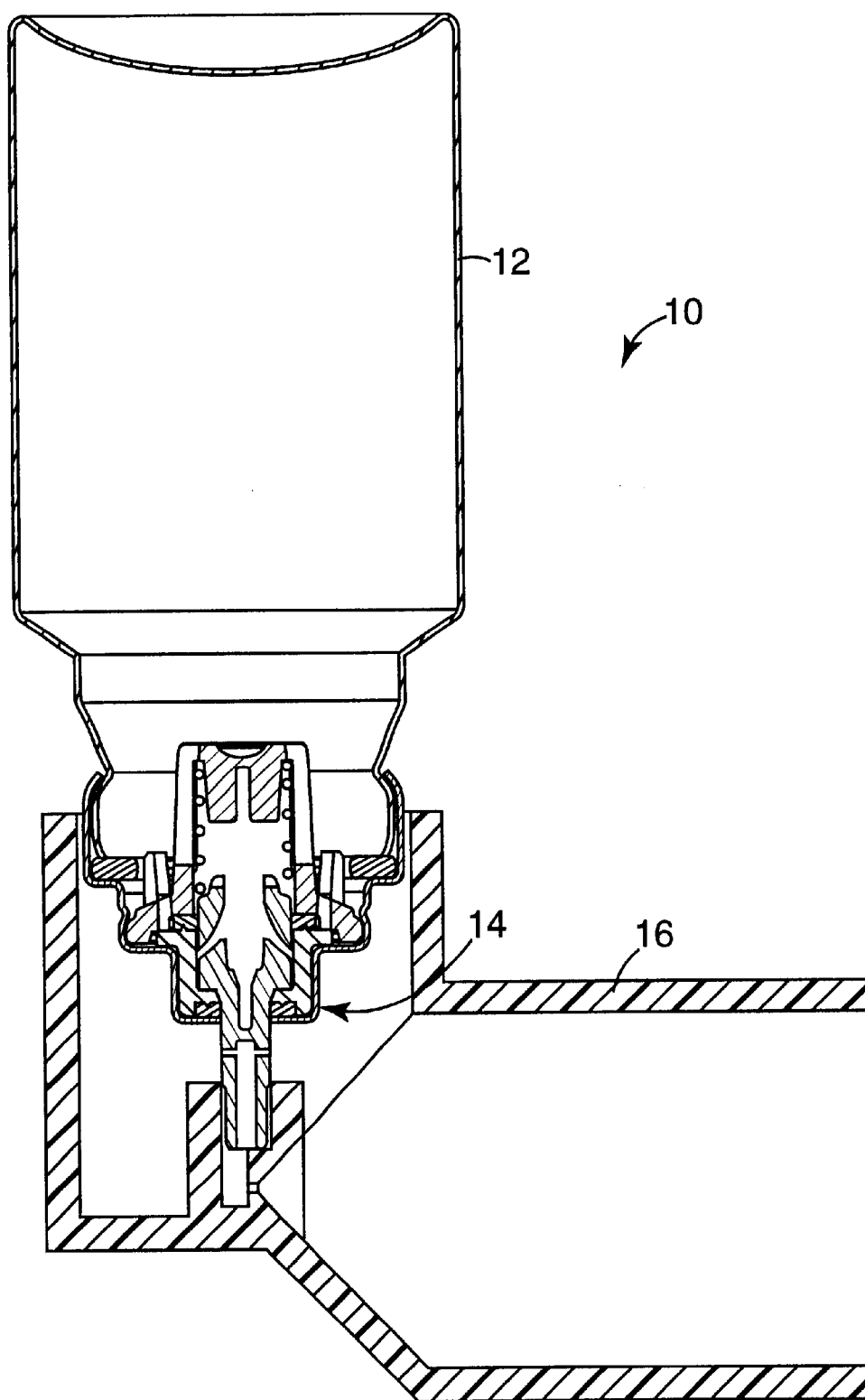


Fig. 1

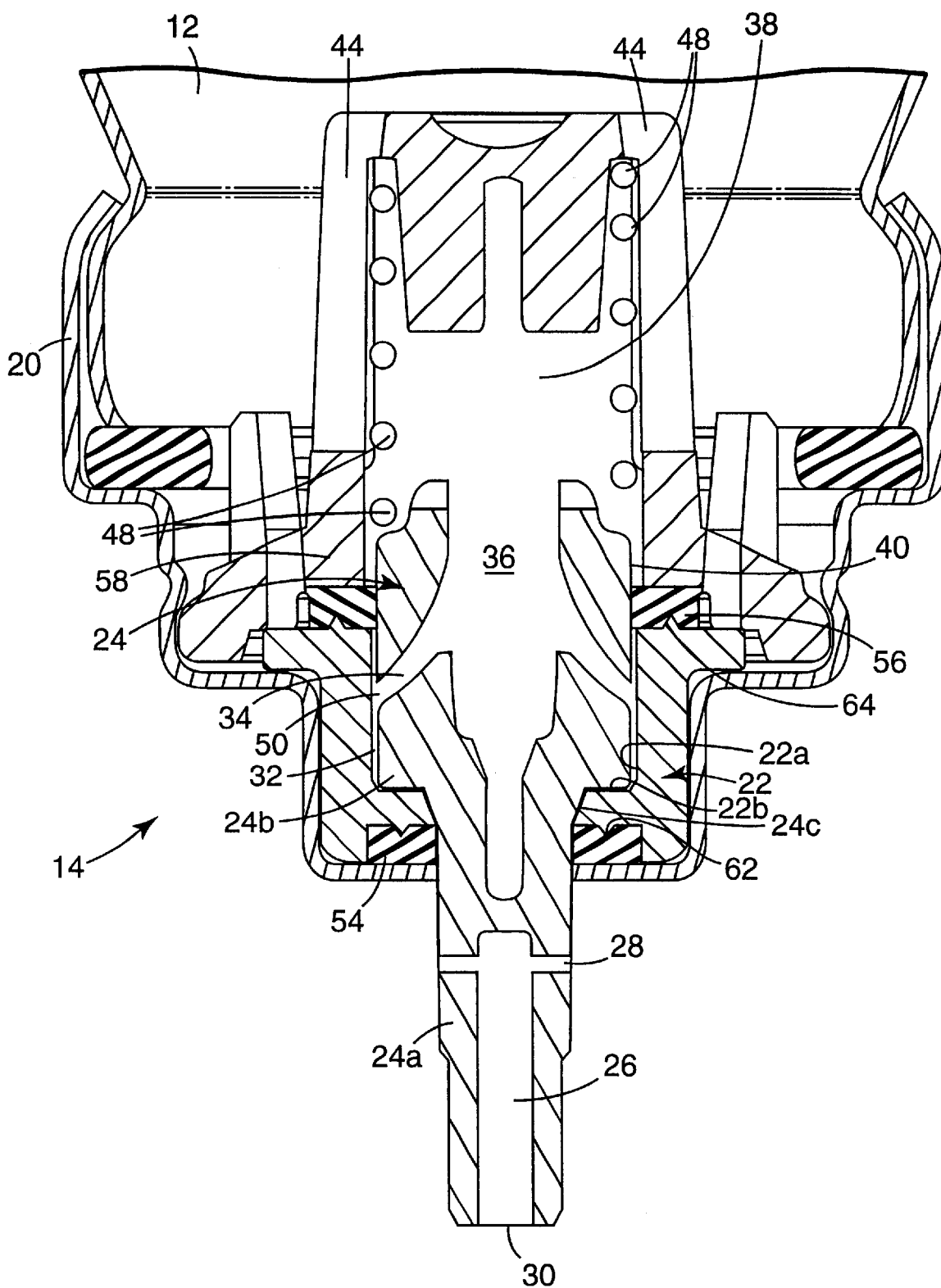


Fig. 2

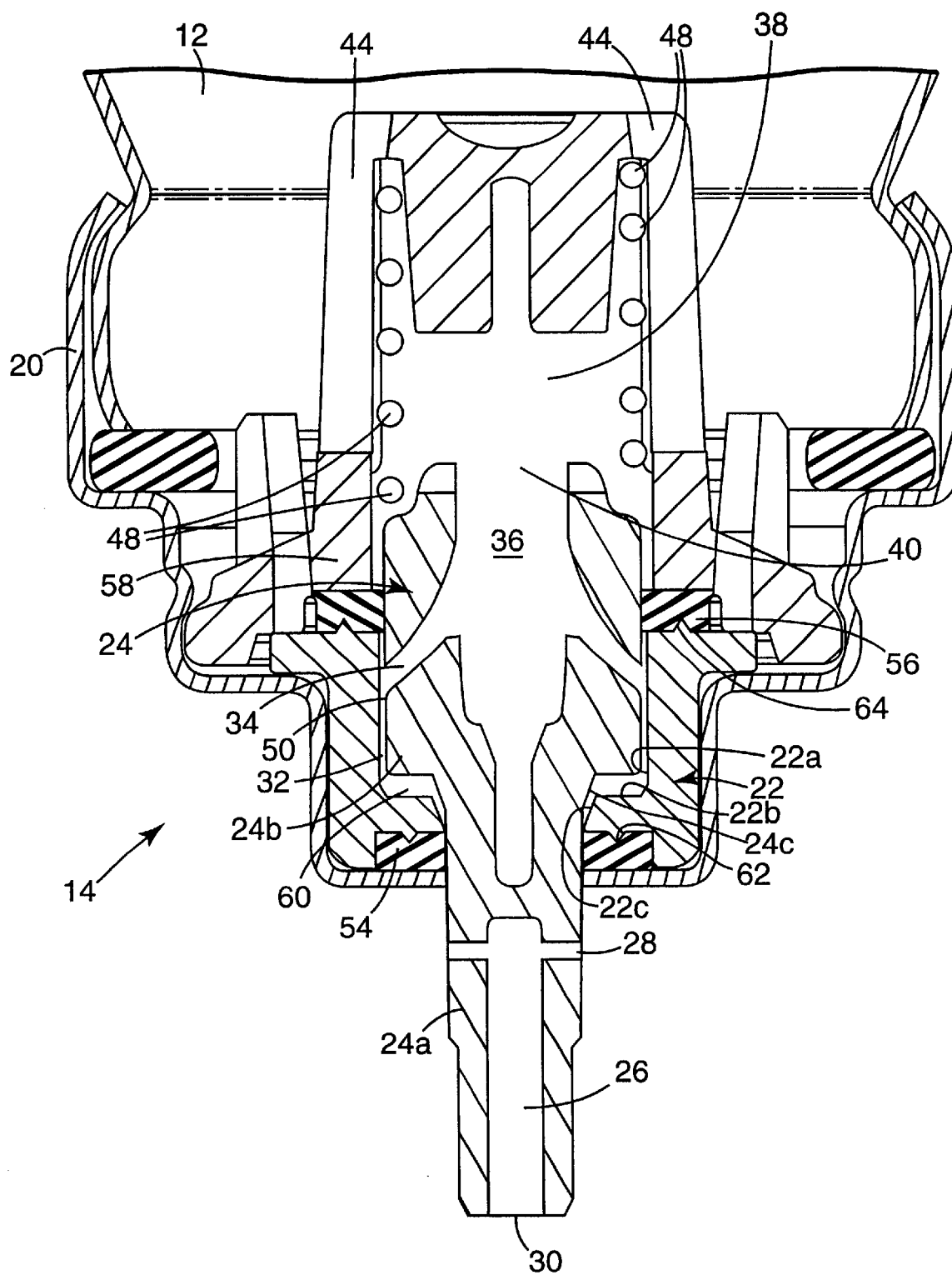


Fig. 3

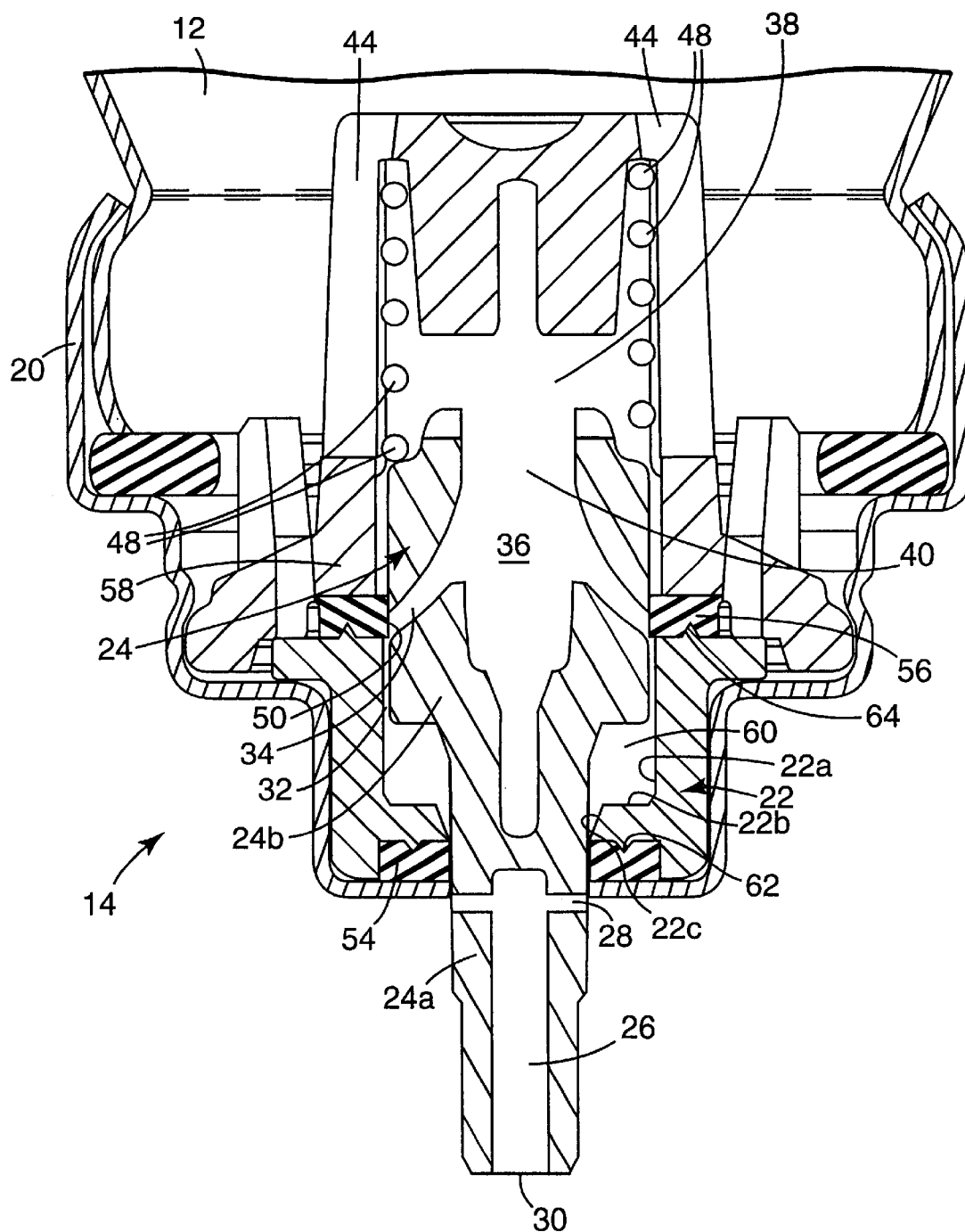


Fig. 4

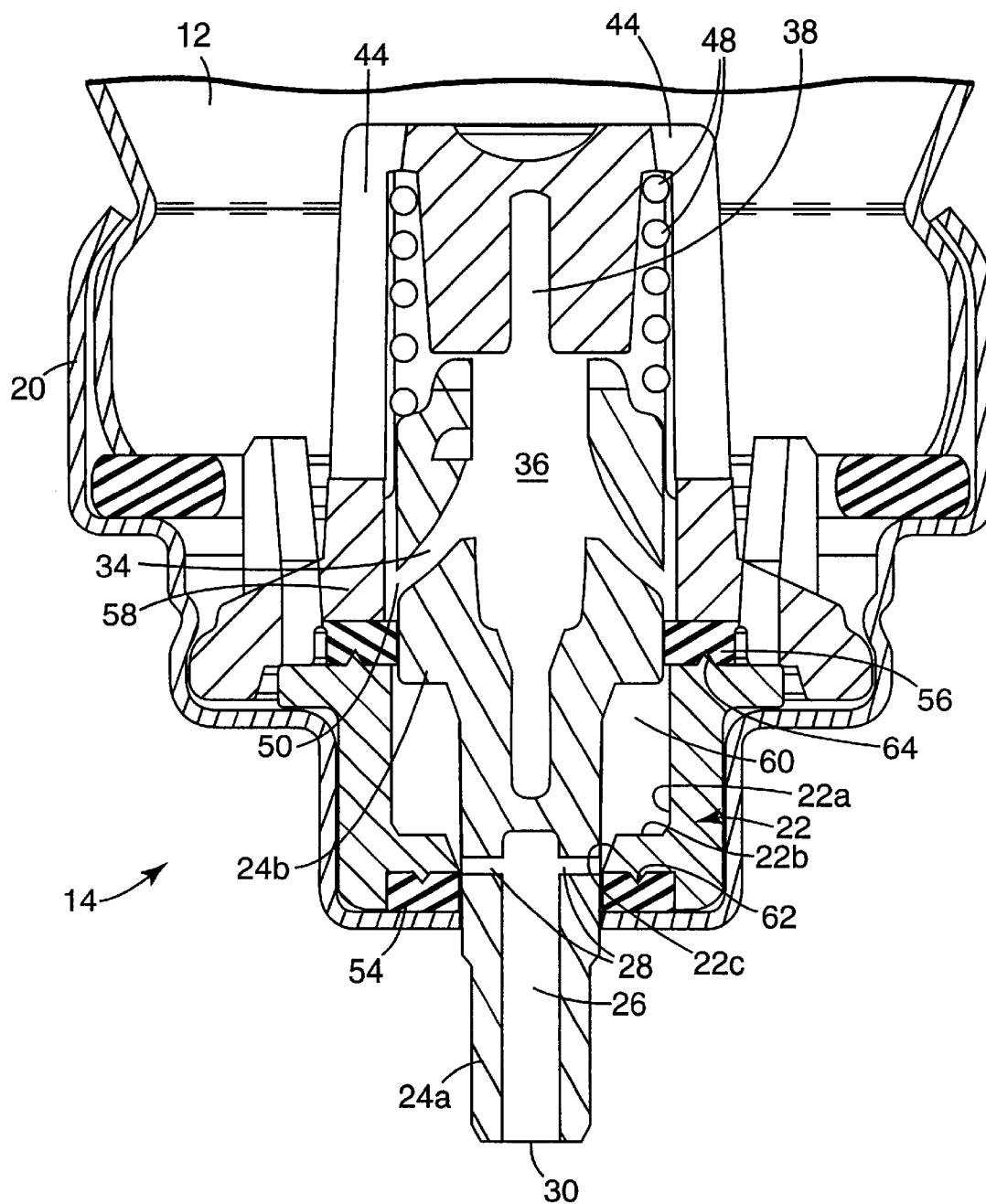


Fig. 5

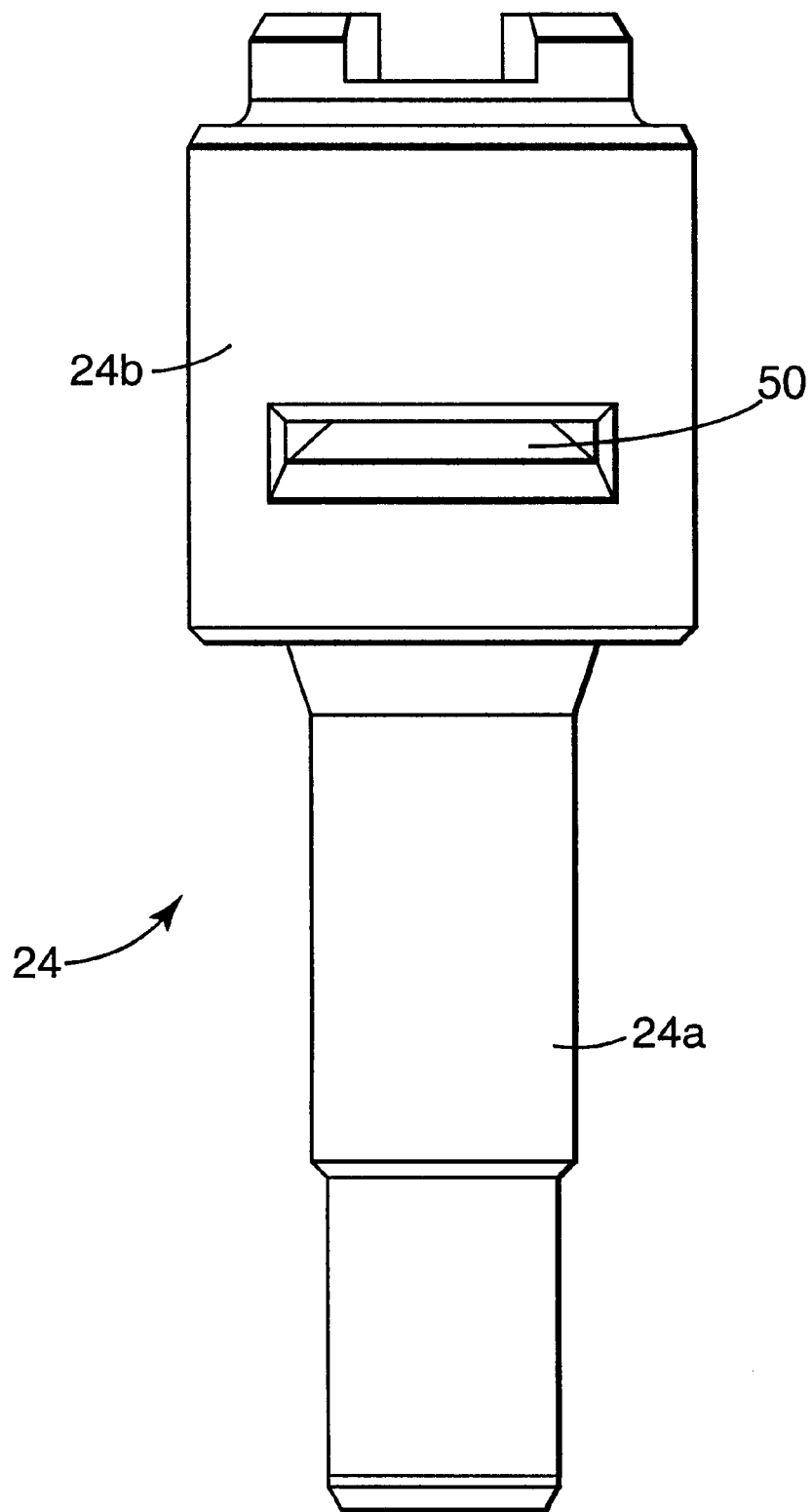


Fig. 6a

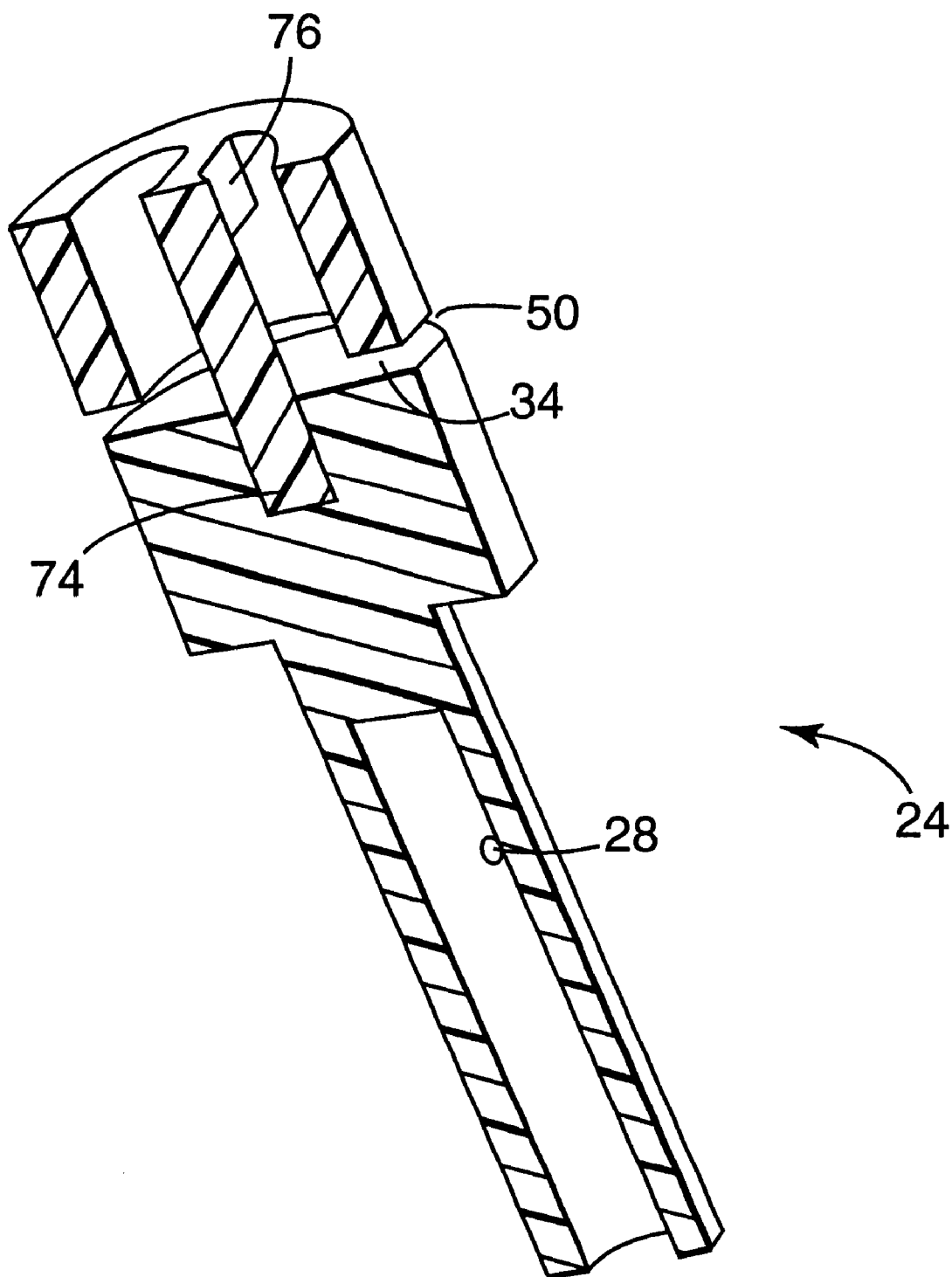


Fig. 6b

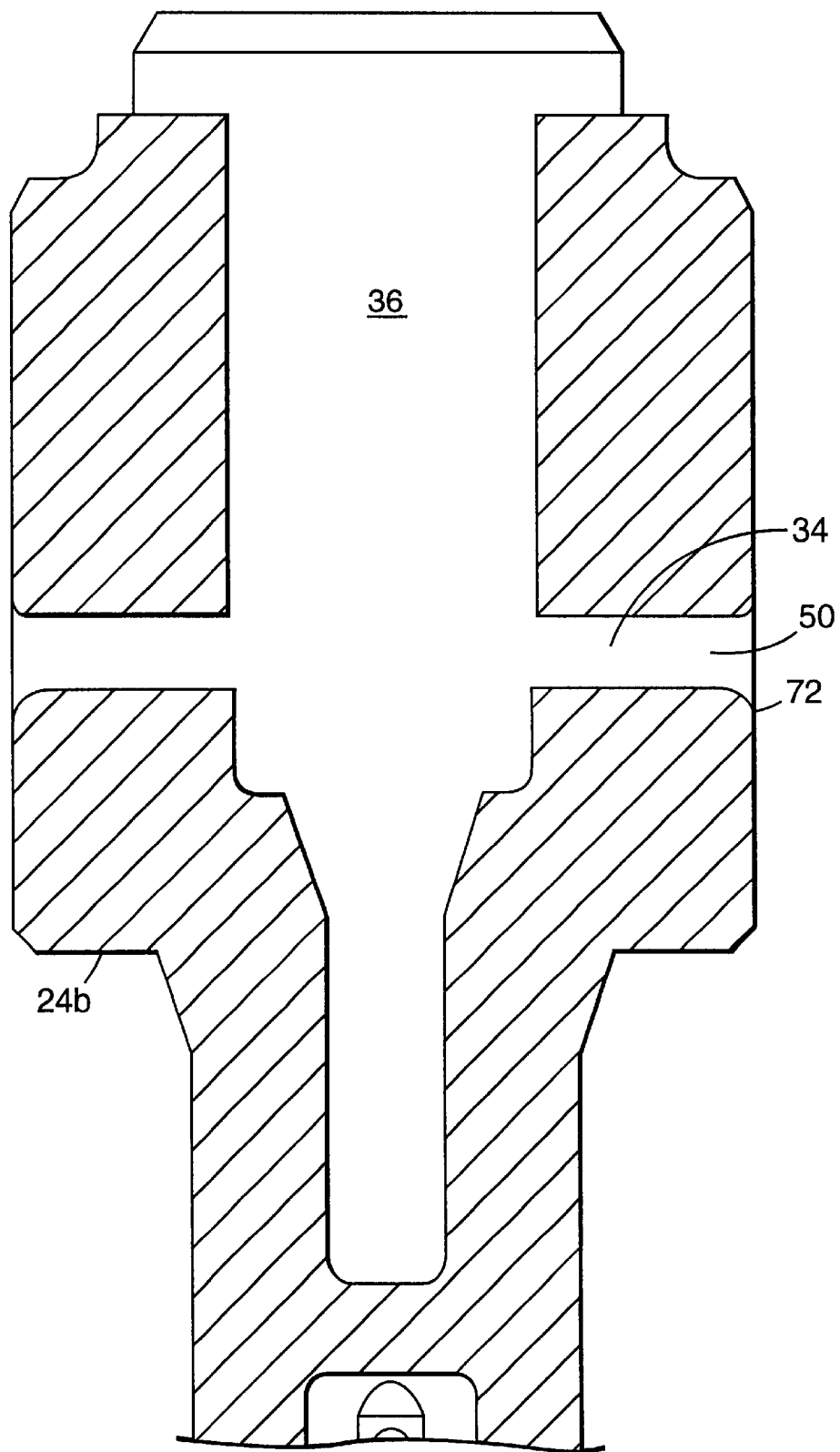


Fig. 7

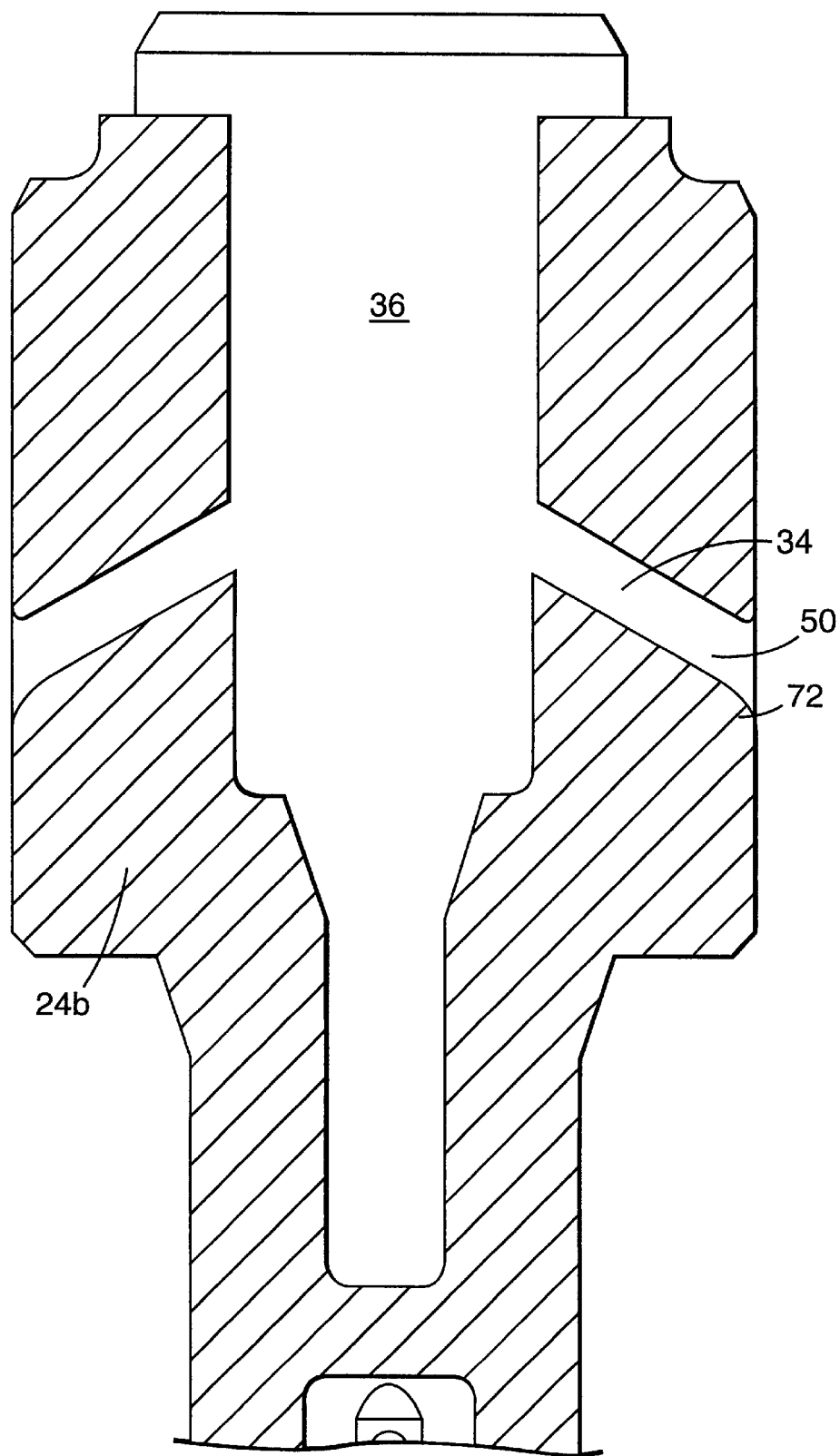


Fig. 8

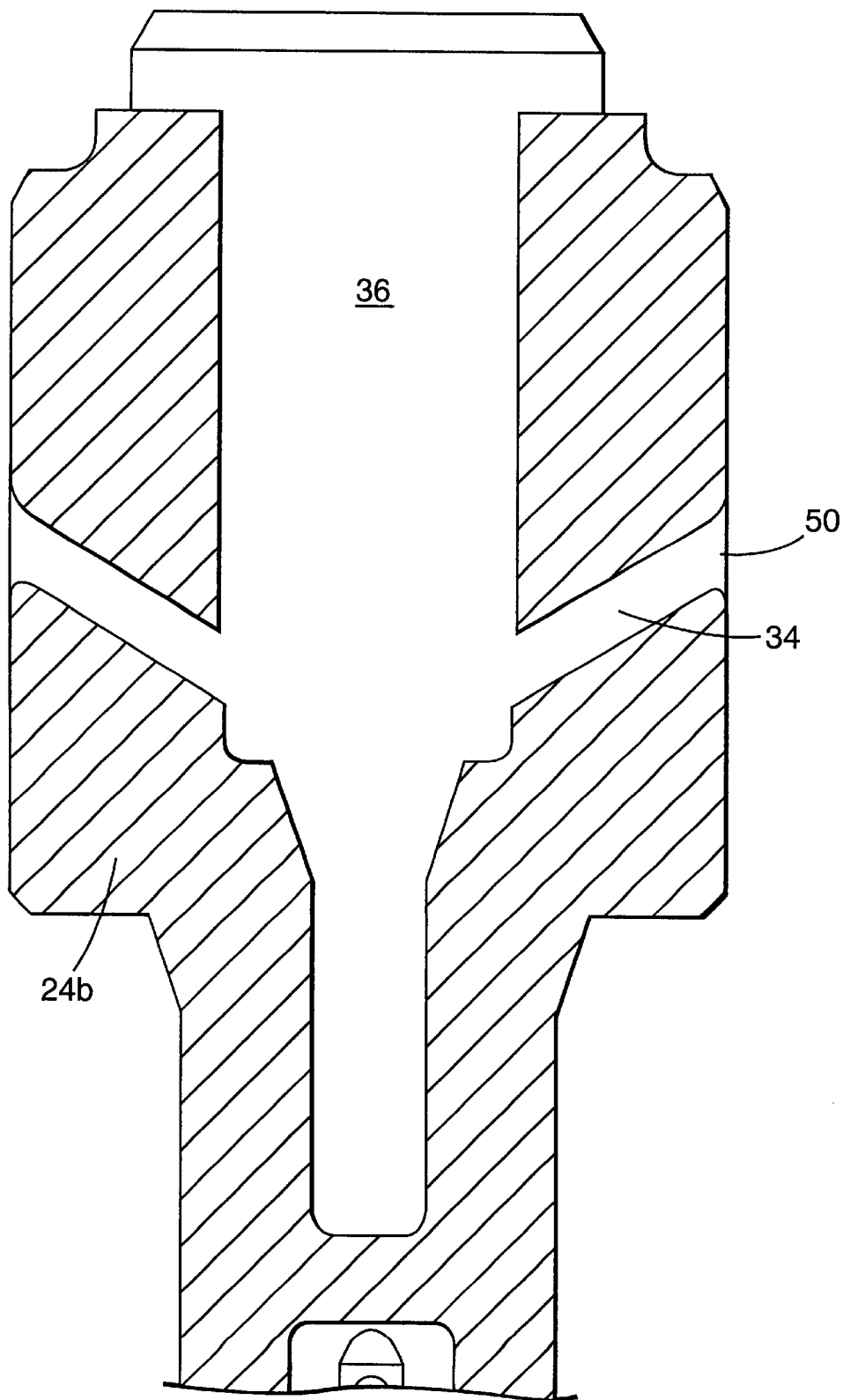


Fig. 9

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**METERING VALVE FOR A METERED DOSE
INHALER HAVING IMPROVED FLOW**

This application claims the benefit of U.S. provisional
patent application Ser. No. 60/278,890, filed Mar. 26, 2001. 5

BACKGROUND

Metering valves are a common means by which aerosols
are dispensed from aerosol containers. Metering valves are
particularly useful for administering medicinal formulations
that include a liquefied gas propellant and are delivered to a
patient in an aerosol. 10

When administering medicinal formulations, a dose of
formulation sufficient to produce the desired physiological
response is delivered to the patient. The proper, predeter-
mined amount of the formulation must be dispensed to the
patient in each successive dose. Thus, any dispensing system
must be able to dispense doses of the medicinal formulation
accurately and reliably to help assure the safety and efficacy
of the treatment. 20

Metering valves have been developed to provide control
over the dispensing of medicinal aerosol formulations. A
metering valve may be used to regulate the volume of a
medicinal formulation passing from a container to a meter-
ing chamber, which defines the maximum amount of the
formulation that will be dispensed as the next dose. The
precise dosage metered by the metering chamber may be
dependent, in part, upon the physical conditions under which
the medicinal formulation is permitted to fill the metering
chamber. Reliable and controllable flow of the medicinal
formulation into the metering chamber may contribute to the
accuracy and/or precision of the metering of successive
doses of the formulation. Thus, reliable and controllable
flow of the medicinal formulation into the metering chamber
may improve performance of the metering valve and,
therefore, may be highly desirable. 30

In some metering valves, the metering chamber fills with
the medicinal formulation prior to the patient actuating the
valve stem and thereby releasing the dose. The metering
chamber is refilled with formulation after dispensing one
dose so that the metering valve is ready to discharge the next
dose. Consequently, the metering chamber contains formu-
lation at all times except for the brief time during which the
valve stem is depressed by the user to discharge a dose. Also,
the passageways through which the formulation must flow to
reach the metering chamber are often narrow and tortuous.
As a result, metering valves configured in this way have a
number of disadvantages resulting in, for example, erratic
dosing due to loss of prime, i.e., the occurrence of vapor or
air voids in the metered volume, which may leading to a
shortfall in the volume of dose being metered by the valve. 40

In other metering valves, the metering chamber does not
materialize unless and until the valve stem is actuated.
Actuation of these valve stems can be divided into a filling
stage and a discharge stage. The filling stage begins as the
valve stem is depressed during actuation. The action of
depressing the valve stem causes the formation of a transient
metering chamber. As the valve stem is depressed, the
transient metering chamber expands and formulation enters
the metering chamber. As displacement of the valve stem
continues, a stage is reached at which filling of the transient
metering chamber stops. Eventually, displacement of the
valve stem continues to the discharge stage, in which the
metered formulation is discharged. In these valves, a single
actuation thus causes rapid filling of the transient metering
chamber followed by discharge of the formulation to the 50

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patient. Thus, the metered formulation does not reside for
any appreciable amount of time in the metering chamber.

While a metering valve having a transient metering cham-
ber provides advantages over other types of metering valves
for the delivery of aerosol formulations, the flow of formu-
lation from the container to the metering chamber may be
disrupted. When this happens, formulation may be delivered
in inconsistent or inaccurate doses.

What is needed is a valve stem for a metered dose inhaler
that improves flow of formulation into the metering
chamber, thereby providing consistent, accurate, dosages of
formulation, even when actuated rapidly.

SUMMARY

15 It has been determined that one cause of disrupted flow of
formulation may be due to the design of the valve stem in the
metering valve. A seal typically isolates the metering cham-
ber from the aerosol container once the correct volume of
formulation has been metered. To accomplish this, the seal
must occlude the flow path, through which formulation must
pass in order to fill the metering chamber, as the valve stem
is depressed beyond the filling stage. As used herein,
occlude refers to at least a partial closing off of an opening
by a seal, gasket, or diaphragm. In certain metering valves,
the passageways leading from the container to the metering
chamber can begin to become occluded well before the
formulation has completed filling the metering chamber.
This effectively begins to cut off flow of formulation into the
metering chamber while the valve stem is still in the filling
stage of actuation. 20

Also, the design of the valve stem may cause regions of
recirculation or localized low pressure to develop in the flow
of formulation into the metering chamber. Such low pressure
regions can lead to incomplete metering of the formulation
by allowing bubbles to form in the metered volume, par-
ticularly when the patient actuates the valve rapidly or rapid
actuation occurs due to the mechanism of a breath actuated
device. 35

The present invention provides a valve stem for a metered
dose inhaler that improves the flow of formulation into the
metering chamber. The novel stem design has a short, but
circumferentially widened channel opening that, in many
embodiments, enhances the flow of formulation into the
metering chamber. Accordingly, the present invention pro-
vides an aerosol valve stem including a body that includes
a body wall defining an internal chamber; at least one inlet
port through the body wall in fluid communication with the
internal chamber; a channel opening in the body wall having
a height and a width wherein the width is greater than the
height; and at least one channel providing fluid communi-
cation between the internal chamber and the channel open-
ing. 45

In some embodiments, the valve stem may include a
plurality of channel openings in the body wall. In these
embodiments, the plurality of channel openings may define
a cumulative width that is greater than the height of the
channel openings.

In another aspect, the present invention provides a method
of delivering an aerosol dose of medicine including provid-
ing an inhaler that includes an aerosol valve stem including:
a body that includes a body wall defining an internal
chamber, at least one inlet port through the body wall in fluid
communication with the internal chamber, a channel open-
ing in the body wall having a height and a width wherein the
width is greater than the height, at least one channel pro-
viding fluid communication between the internal chamber 60

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and the channel opening; providing a formulation of aerosol medicine contained within the inhaler; and actuating the inhaler.

In yet another aspect the present invention provides a metering valve that includes a housing that includes an internal chamber defined by one or more chamber walls, the internal chamber comprising an outlet aperture; a diaphragm positioned at the outlet aperture and in sealing engagement with at least a portion of the housing; a metering gasket in sealing engagement with one or more chamber walls; a valve stem including: i) a body that comprises a body wall defining an internal chamber, ii) at least one inlet port through the body wall in fluid communication with the internal chamber, iii) a channel opening in the body wall having a height and a width wherein the width is greater than the height, and iv) at least one channel providing fluid communication between the internal chamber and the channel opening, wherein the valve stem passes through the aperture in slidable sealing engagement with both of the diaphragm and the metering gasket; and an annular space having a width defined by a distance between the chamber wall and the valve stem.

In some embodiments, the valve stem may include a plurality of channel openings in the body wall. In these embodiments, the plurality of channel openings may define a cumulative width that is greater than the height of the channel openings. In certain embodiments, the height of at least one channel opening may be from about 1 to about 5 times the width of the annular space.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a metered dose inhaler including the aerosol valve of the present invention.

FIG. 2 is an enlarged cross-sectional view of the aerosol valve of the present invention in the resting position.

FIG. 3 is an enlarged cross-sectional view of the aerosol valve of the present invention during the filling stage of valve stem actuation.

FIG. 4 is an enlarged cross-sectional view of the aerosol valve of the present invention in the filled stage of valve stem actuation.

FIG. 5 is an enlarged cross-sectional view of the aerosol valve of the present invention during the discharge stage of valve stem actuation.

FIG. 6a is a side view of an alternative embodiment of the aerosol valve stem of the present invention.

FIG. 6b is a view of a half section of an alternative embodiment of the aerosol valve stem of the present invention.

FIG. 7 is an enlarged cross-section of an alternative embodiment of the aerosol valve stem of the present invention.

FIG. 8 is an enlarged cross-section of another alternative embodiment of the aerosol valve stem of the present invention.

FIG. 9 is an enlarged cross-section of another alternative embodiment of the aerosol valve stem of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The following description is set forth in terms of aerosol metering valves used to dispense an aerosol formulation from an aerosol container. However, the metering valves and

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methods of the present invention have application to the delivery of virtually any pressurized fluid in an accurate, metered dose. In particular, the metering valves described herein are useful for dispensing medicinal aerosol formulations.

When used to dispense medicinal aerosol formulations, the metering valves of the present invention may be used to administer virtually any aerosol formulation of drug into a body cavity of a patient, such as the mouth, nose, anus, vagina, ears, or onto the eyes or any skin area of the patient. However, the present invention is not limited to medicinal applications and may be used wherever a precise amount of material from a pressurized fluid is to be delivered to a given region.

Referring to FIG. 1, an aerosol dispensing apparatus, generally designated as 10, is illustrated that incorporates one embodiment of a metering valve 14 in accordance with the present invention. The top end of the metering valve 14 is crimped around the end of a conventional aerosol container 12, while a conventional discharge piece 16 is mounted around the bottom of the metering valve 14. Thus, aerosol formulation is dispensed downwardly from the aerosol container 12, through the metering valve 14, then through the discharge piece 16 where it is delivered to a patient. The discharge piece 16 directs the aerosol formulation toward the body cavity or skin area to which the formulation is to be delivered. The configuration of the discharge piece 16 depends upon the application for the aerosol. For example, discharge piece 16 may be a mouthpiece that can be inserted into the patient's mouth, thereby providing oral administration of the aerosol formulation. The aerosol-dispensing device shown in FIG. 1 is merely one example of how a metering valve according to the present invention can be incorporated into a dispensing apparatus.

In each of FIGS. 2-5, a metering valve is shown in isolation for ease of illustration. However, the metering valves shown in these figures may be combined with an aerosol container 12, discharge piece 16, or both, as shown in FIG. 1.

Referring to FIG. 2, the metering valve 14 is shown in the resting position. The metering valve 14 includes a housing 20 that serves to house the various components of the metering valve 14. The top portion of the housing 20 attaches to the aerosol container 12 (as shown in FIG. 1). A valve body 22 is seated within the valve housing 20 and in turn provides a housing for a valve stem 24.

The metering valve 14 may include a spring cage 58 defining an interior chamber 38, a portion of which is occupied by the valve stem 24. One or more inlets 44 provide open and unrestricted fluid communication between the interior chamber 38 and the aerosol container 12.

The valve stem 24 includes two portions, identified as 24a and 24b. The external portion of the valve stem 24a is that portion of the valve stem 24 that is positioned outside the valve housing 20 while the valve stem 24 is in the resting position shown in FIG. 2. During actuation of the valve stem 24, however, at least some of the external valve stem 24a is displaced inwardly with respect to the metering valve 14, as described more fully below, so that a portion of the external valve stem 24a is transiently positioned inside the valve housing 20. The internal valve stem 24b is that portion of the valve stem 24 that is positioned within the valve housing 20 throughout actuation of the valve stem 24.

The external valve stem 24a includes a passageway through which a metered dose of formulation is discharged,

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as will be described more fully below. The passageway may include one or more side holes 28, a discharge passageway 26 and a discharge opening 30.

The internal valve stem 24b may be configured to have substantially the same shape as, but to be slightly smaller than, the surrounding wall of the valve body 22a. Thus, a narrow annular space 32 may be formed between the valve body wall 22a and the internal valve stem 24b. In certain embodiments in which the valve stem 24 and the valve body wall 22a are both circular in cross-section, the narrow annular space 32 may form a ring. However, the valve stem 24 and valve body wall 22a, and therefore the narrow annular space 32, may be any suitable shape. The internal valve stem 24b includes an interior space 36 defined by the walls of the valve stem 24. One or more channels 34 are formed in the walls of the internal valve stem 24b and provide fluid communication between the interior space 36 and the narrow annular space 32 through one or more channel openings 50.

In the resting position shown in FIG. 2, the internal valve stem 24b fits concentrically inside the valve body 22 and provides sufficient clearance for the narrow annular space 32. Accordingly, only a small percentage of the metering chamber volume is present in the metering valve 14 while it is in the resting position shown in FIG. 2. As will be described in greater detail below, when the valve stem 24 is actuated, the valve stem 24 is displaced into the interior chamber 38 of the metering valve 14 and a space is created between the internal valve stem 24b and the floor of the valve body 22b. The space thus created is the metering chamber 60, as shown in FIG. 3.

In the embodiment shown in FIG. 2, a spring 48 is provided within the interior chamber 38 of the metering valve. The spring 48 serves to bias the valve stem 24 toward the resting position shown in FIG. 2. However, any suitable means for biasing the valve stem 24 into the resting position shown in FIG. 2 may be used in connection with the present invention.

The metering valve 14 also includes at least two annular gaskets, the housing gasket 54 and the metering gasket 56. The housing gasket 54 is positioned between the valve housing 20, the valve body 22 and the valve stem 24, as shown in FIG. 2. The housing gasket 54 isolates the formulation in the aerosol container 12 from the exterior of the valve by forming two fluid tight seals: 1) an annular seal between the housing gasket 54 and the valve stem 24 where the valve stem extends out of the valve housing, and 2) a compressive planar or face seal between the housing gasket 54 and the housing 20. The latter seal may be effected either with or without a sealing bead 62 on either the valve body 22 or the housing 20.

The valve body 22 may include an angled shoulder 22c, which is best seen in FIG. 3 and is designed to support the housing gasket 54 near the valve stem 24 while functioning to direct the flow of formulation out of the metering chamber 60 during the discharge stage shown in FIG. 5. The valve stem 24 may include an angled shoulder 24c designed to match the profile of the valve body 22, thereby minimizing the amount of formulation present in the metering chamber 60 in the resting position shown in FIG. 2.

The metering gasket 56 may be positioned between the valve body 22, the spring cage 58, and the internal part of the valve stem 24b. The metering gasket 56 transiently isolates the formulation in the metering chamber 60 from the aerosol container 12, as shown in FIGS. 4 and 5, by forming two fluid tight seals: 1) an annular seal between the metering

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gasket 56 and the internal part of the valve stem 24b, and 2) a compressive planar or face seal between the metering gasket 56 and the valve body 22. The latter seal may be effected either with or without a sealing bead 64 on either the valve body 22 or the spring cage 58. The metering gasket 56 provides a means for terminating the flow of formulation from the aerosol container 12 to the metering chamber 60 during actuation of the valve stem 24, as will be described in more detail below.

The operation of the metering valve 14 shown in FIG. 2 is illustrated in FIGS. 3, 4 and 5. The figures illustrate the stages of operation of the metering valve 14 and the corresponding relative positions of the valve components as a patient actuates the valve stem 24, thereby releasing a dose of aerosol formulation. FIG. 3 shows the metering valve 14 in the filling stage, FIG. 4 shows the metering valve 14 in the filled stage, and FIG. 5 shows the metering valve 14 in the discharge stage.

FIG. 3 illustrates the filling stage of the metering valve 14. The valve stem 24 has been displaced inwardly into the interior chamber 38 against the compressive force of the spring 48. As the valve stem 24 is displaced inwardly, the proximal end of the external stem 24a enters the valve housing 20 such that an annular space, the metering chamber 60, is formed between the valve body 22 and the valve stem 24. The volume of the metering chamber 60 increases as the valve stem is displaced. Displacement of the valve stem 24 typically continues until the valve stem 24 reaches a "filled" position, depicted in FIG. 4.

The aerosol formulation enters the metering chamber 60 in the following manner. Formulation from the aerosol container 12 passes through the one or more metering valve inlets 44 and into the interior chamber 38 of the metering valve. From the interior chamber 38, the formulation passes through the valve stem inlet port 40 and enters the valve stem interior space 36. Formulation then passes through one or more channels 34, one or more channel openings 50 and the narrow annular space 32, into the metering chamber 60. Consequently, as the valve stem 24 is moved from the resting position shown in FIG. 2 to the filling stage shown in FIG. 3, aerosol formulation passes from the aerosol container 12 to the metering chamber 60 immediately upon actuation of the valve stem 24. Formulation continues to fill the metering chamber 60 until the metering valve 14 reaches the filled stage depicted in FIG. 4.

FIG. 4 illustrates the metering valve 14 in the filled stage. The flow path of formulation from the aerosol container 12 to the metering chamber 60 becomes occluded as the metering gasket 56 moves past the channel opening 50. Ultimately, the channel opening 50 is fully occluded by the metering gasket 56, as shown in FIG. 4, and the flow of formulation into the metering chamber 60 is cut off, thereby concluding filling of the metering chamber 60.

Upon further actuation, the metering gasket 56 forms a fluid seal around the valve stem 24 that prevents any additional flow of formulation to the metering chamber 60. At this stage, the metered dose of formulation is isolated and ready for discharge from the metering chamber 60 and delivery to the patient. The dimensions of the valve body 22, valve stem 24 and other valve components determine the volume of the metering chamber 60 in the filled position depicted in FIG. 4. The valve body 22, valve stem 24 and other valve components may be designed to permit largely unimpeded flow of formulation during the filling stage while preventing unintended continuous discharge of formulation subject to the dimension tolerances of the valve components.

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FIG. 5 depicts the metering valve 14 in the discharge stage of actuation. In order to discharge the metered dose of aerosol formulation from the metering chamber 60, the valve stem 24 may be further actuated to the position illustrated in FIG. 5. The distance traveled by the valve stem 24 between FIG. 4 and FIG. 5 may result in an expansion of the metering chamber volume without adding to the metered dose of formulation because of the seal formed between the metering gasket 56 and the valve stem 24, described above. The extra travel ensures that the metering gasket 56 is sealed against the valve stem 24 before the one or more side holes 28 enter the metering chamber 60. This extra travel thus serves to allow for dimensional variations in the valve components.

As the valve stem 24 is fully actuated, the one or more side holes 28 of the discharge passageway 26 pass through the housing gasket 54 and come into fluid communication with the metering chamber 60. That fluid communication allows the aerosol formulation within the metering chamber 60 to be released into the one or more side holes 28 and the formulation thus passes through the discharge passageway 26 and out of the discharge opening 30, thereby delivering the metered dose of aerosol formulation to the patient or other desired area.

During the discharge of the aerosol formulation from the metering chamber 60 as shown in FIG. 5, the metering gasket 56 continues to prevent the passage of additional bulk formulation from the aerosol container 12 to the metering chamber 60. After the dose of aerosol formulation is discharged, the patient releases the valve stem 24, which returns to its original resting position depicted in FIG. 2 by the biasing action of the spring 48.

The successive stages of valve stem actuation depicted in FIGS. 2, 3, 4 and 5 are all accomplished during the brief duration of actuation of the valve stem 24. Accordingly, formation, filling and emptying of the metering chamber 60 occurs rapidly. Only a small percentage of a dose of formulation resides in the metering chamber 60 between discharges, and the metering chamber 60 contains a fully metered dose of formulation only for a brief moment immediately prior to discharge of the dose from the metering chamber 60. Subsequent release of the valve stem by the patient allows the valve to return from the position depicted in FIG. 5 to that depicted in FIG. 2.

Because the valve body 22, valve stem 24 and other valve components together define the volume of the metering chamber 60, the metering valve components may be designed to form a metering chamber 60 having an appropriate metering volume for any desired application. Furthermore, metering valves having different capacities may be manufactured by, for example, altering the relative position of the channels 34 and channel opening 50 along the wall of the internal valve stem 24b. The volume of the metering chamber 60 at any moment is defined, in part, by the extent to which the valve stem 24 is displaced inwardly with respect to the metering valve 14.

The volume of the metering chamber 60 at the moment that the metering gasket 56 fully occludes the channel opening 50 defines the filling capacity of the metering chamber 60. Therefore, a metering valve in which the metering gasket 56 fully occludes the channel opening 50 relatively early in the displacement of the valve stem 24 will have a smaller filling capacity than a metering valve in which the metering gasket 56 fully occludes the channel opening 50 relatively late in displacement of the valve stem 24.

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The channel opening 50 is defined by an axial dimension and a circumferential dimension as shown in FIG. 6a. As used herein, the axial dimension, or height, is the dimension parallel to the direction of displacement of the valve stem 24 during actuation. As used herein, the circumferential dimension, or width, is the dimension parallel to the circumference of the valve stem 24.

In one embodiment, at least one channel opening 50 has a cross-sectional width that is greater than its height, thereby constituting a wide, short channel opening 50. Certain embodiments of the present invention have a channel opening having a height of about 0.25 mm, some have a channel opening with a height of about 0.5 mm, and other embodiments may have a channel opening having any height ranging from about 0.01 mm to about 1.0 mm. Embodiments having a channel opening having a height from about 0.1 mm to about 0.8 mm have been identified as being particularly useful.

Certain embodiments of the present invention may have multiple channel openings 50. In such embodiments, the multiple channel openings may form a discontinuous functional equivalent of the channel opening 50 of the present invention even though no individual channel opening has a width greater than its height. In such an arrangement, the sum of the channel opening widths may define a cumulative width. Such embodiments having multiple channel openings 50 that define a cumulative circumferential width that is greater than the height of the openings are included in the scope of the present invention.

Certain other embodiments may have a single channel opening 50 that completely encircles the valve stem 24. In these embodiments, the width of the channel opening 50 essentially equals the circumference of the valve stem 24. An example of such an embodiment is depicted in FIG. 6b, which shows a view of a half section of a valve stem 24. While the channel opening 50 completely encircles the valve stem 24, one or more internal supports 76 join two halves of the valve stem. Sophisticated internal geometries may be manufactured by forming the valve stem 24 as two separate components that can be joined together. The components may be joined by any suitable means such as press-fitting or crimping, for example. In the embodiment shown in FIG. 6b, a lug 74 on the upper part of the valve stem 24 fits into a corresponding hole in the lower part of the valve stem 24.

A short channel opening height maximizes the proportion of the displacement of the valve stem 24 during actuation before the metering gasket 56 begins to occlude the channel opening 50. Thus, nearly all of the formulation enters the metering chamber 60 via steady flow before the channel opening 50 begins to be fully occluded by the metering gasket 56. This may reduce the potential effects of actuation speed with respect to filling performance. A channel opening 50 covering a large portion of the circumference of the valve stem 24 allows a large cross-sectional area for filling the annular space 32, thereby increasing the reliability and precision of the metering of the formulation. A channel opening having the combination of a wide circumference and short height may provide a desirable balance between maximizing the cross-sectional surface area of the channel opening and also maximizing the proportion of the distance the valve stem 24 travels before the channel opening 50 begins to become occluded by the metering gasket 56.

The relationship between height of the channel opening 50 and the width of the narrow annular space 32 also may influence the filling characteristics of the metering valve 14. Generally, a channel opening height of about one to about

five times the width of the narrow annular space **32** permits steady flow of the formulation into the metering chamber **60** until approximately one half of the channel opening **50** is occluded by the metering gasket **56**. Certain embodiments of the present invention include a channel opening height that is about three times the width of the annular space **32**.

A channel opening height of greater than about five times the width of the annular space **32** may cause recirculation of flow as the metering chamber **60** fills. As used herein, recirculation refers to flow circulating or flowing back against the general direction of the flow path in a localized region within a moving fluid. Recirculating formulation may interrupt the steady flow of formulation, at least in the vicinity of the recirculating flow. This may result in at least a temporary decrease in the effective cross-sectional area of the channel opening **50** available to conduct flow of formulation, thereby reducing the rate at which formulation is allowed to flow into the metering chamber **60**.

The channel **34** may intersect the channel opening **50** (the channel angle) at about a 0° angle with respect to the horizontal plane of the valve stem, as shown in FIG. 7, or at an inclined angle, as shown in FIG. 8. In one embodiment, similar to that shown in FIG. 7, the channel **34** may intersect with the channel opening **50** at about a 0° angle relative to the horizontal plane of the valve stem **24** and have a channel opening **50** measuring about 0.25 mm in height and about 280° of the valve stem circumference. An alternative embodiment may have a channel opening height of about 0.5 mm.

The channel angle may range from about +90° to about -90° with respect to the horizontal plane of the valve stem. An angled channel **34** may help direct the flow formulation into the narrow annular space **32** (see FIG. 3). This, in turn, may minimize the region of low pressure that may develop as the formulation passes through the channel opening **50** and into the narrow annular space **32**. Such regions of low pressure can increase the likelihood of bubble formation within the formulation. In one embodiment, similar to that shown in FIG. 8, the channel angle may be about +45° relative to the horizontal plane of the valve stem **24** and the channel opening **50** may measure about 0.25 mm in height and about 160° of the valve stem circumference. An alternative embodiment may have a channel opening height of about 0.5 mm. Any channel angle from about 0° to and including about +90°, relative to the horizontal plane of the valve stem, may be suitable for a particular application, however.

In an alternative embodiment, a channel may intersect with the channel opening **50** at an angle from about 0° to about -90° with respect to the horizontal plane may be desired in certain embodiments. Such an embodiment, similar to that shown in FIG. 9, may have a channel angle of about -45° with respect to the horizontal plane of the valve stem, for example. Drug from a suspension formulation may form a sediment between dosings. In the embodiment shown in FIG. 9, such sedimented drug may preferentially collect on the floor of interior space **36**, thereby reducing sedimentation of drug in the channels **34**, the narrow annular space **32**, or both. The sedimented drug may be more readily resuspended into the formulation from the floor of the interior space **36** than from either the channels **34** or the narrow annular space **32** when the patient shakes the inhaler. Thus, such a valve stem may promote more consistent, accurate dosing and more complete use of drugs in suspension formulations. Any channel angle from about 0° to and including about -90° may be suitable for a particular application.

In certain embodiments, one or more edges **72** of the channel opening **50** may be beveled or rounded, as shown in FIG. 7. Edges **72** modified in this way may provide a smooth transition of the flow path from the channel **34** into the narrow annular space **32**. This feature also may contribute to reducing the likelihood and extent to which localized regions of low pressure will develop in the flow of formulation. Consequently, beveled or rounded edges of the channel opening **50** may help reduce the likelihood of bubble formation within the formulation.

Various modifications and alterations to this invention will become apparent to those skilled in the art without departing from the scope and spirit of this invention. It should be understood that this invention is not intended to be unduly limited by the illustrative embodiments and examples set forth herein and that such examples and embodiments are presented by way of example only with the scope of the invention intended to be limited only by the claims set forth herein as follows.

What is claimed is:

1. An aerosol valve stem comprising:

a body comprising a body wall defining an internal chamber;

at least one inlet port through the body wall in fluid communication with the internal chamber;

a channel opening in the body wall having a height and a width wherein the width is greater than the height; and at least one channel providing fluid communication between the internal chamber and the channel opening.

2. The aerosol valve stem of claim 1 wherein the height of the channel opening is from about 0.01 mm to about 1.0 mm.

3. The aerosol valve stem of claim 2 wherein the height of the channel opening is from about 0.1 mm to about 0.8 mm.

4. The aerosol valve stem of claim 2 wherein the height of the channel opening is about 0.25 mm.

5. The aerosol valve stem of claim 1 wherein the channel opening completely encircles the valve stem.

6. The aerosol valve stem of claim 1 wherein the channel opening comprises at least one rounded edge or at least one beveled edge.

7. The aerosol valve stem of claim 1 wherein at least one channel intersects with at least one channel opening at an angle of from about +90° to about -90° relative to a horizontal axis of the valve stem.

8. The aerosol valve stem of claim 7 wherein at least one channel intersects with at least one channel opening at an angle of from about +45° to about -45° relative to a horizontal axis of the valve stem.

9. The aerosol valve stem of claim 7 wherein at least one channel intersects with at least one channel opening at an angle of about 0° relative to a horizontal axis of the valve stem.

10. An aerosol valve stem comprising:

a body comprising a body wall defining an internal chamber;

at least one inlet port through the body wall in fluid communication with the internal chamber;

a plurality of channel openings in the body wall, each channel opening having a height and a width wherein at least two channel openings define a cumulative width, and wherein the cumulative width is greater than the height; and

at least one channel providing fluid communication between the internal chamber and each channel opening.

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11. The aerosol valve stem of claim 10 wherein the height of at least one channel opening is from about 0.01 mm to about 1.0 mm.

12. A method of delivering an aerosol dose of medicine comprising:

- a) providing an inhaler that comprises a valve stem comprising:
 - i) a body comprising a body wall defining an internal chamber,
 - ii) at least one inlet port through the body wall in fluid communication with the internal chamber,
 - iii) a channel opening in the body wall having a height and a width wherein the width is greater than the height, and
 - iv) at least one channel providing fluid communication between the internal chamber and the channel opening;
- b) providing a formulation of aerosol medicine contained within the inhaler; and
- c) actuating the inhaler.

13. A method of delivering an aerosol dose of medicine comprising:

- a) providing an inhaler that comprises a valve stem comprising:
 - i) a body comprising a body wall defining an internal chamber,
 - ii) at least one inlet port through the body wall in fluid communication with the internal chamber,
 - iii) a plurality of channel openings in the body wall, each channel opening having a height and a width wherein at least two channel openings define a cumulative width, and wherein the cumulative width is greater than the height, and
 - iv) at least one channel providing fluid communication between the internal chamber and each channel opening;
- b) providing a formulation of aerosol medicine contained within the inhaler; and
- c) actuating the inhaler.

14. A metering valve comprising:

a housing comprising an internal chamber defined by one or more chamber walls, the internal chamber comprising an outlet aperture;

a diaphragm positioned at the outlet aperture and in sealing engagement with at least a portion of the housing;

a metering gasket in sealing engagement with one or more chamber walls;

a valve stem comprising:

- i) a body comprising a body wall defining an internal chamber,
- ii) at least one inlet port through the body wall in fluid communication with the internal chamber,
- iii) a channel opening in the body wall having a height and a width wherein the width is greater than the height, and
- iv) at least one channel providing fluid communication between the internal chamber and the channel opening,

wherein the valve stem passes through the aperture in slidable sealing engagement with both of the diaphragm and the metering gasket; and
an annular space having a width defined by a distance between the chamber wall and the valve stem.

15. The metering valve of claim 14 wherein the height of the channel opening is from about 1 to about 5 times the width of the annular space.

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16. The metering valve of claim 14 wherein the height of the channel opening is about 3 times the width of the annular space.

17. The metering valve of claim 14 wherein the height of the channel opening is from about 0.01 mm to about 1.0 mm.

18. The metering valve of claim 17 wherein the height of the channel opening is from about 0.1 mm to about 0.8 mm.

19. The metering valve of claim 17 wherein the height of the channel opening is about 0.25 mm.

20. The metering valve of claim 14 wherein the channel opening completely encircles the valve stem.

21. The metering valve of claim 14 wherein the channel opening comprises at least one rounded edge or at least one beveled edge.

22. The metering valve of claim 14 wherein at least one channel intersects with at least one channel opening at an angle of from about +90° to about -90° relative to a horizontal axis of the valve stem.

23. The metering valve of claim 22 wherein at least one channel intersects with at least one channel opening at an angle of from about +45° to about -45° relative to a horizontal axis of the valve stem.

24. The metering valve of claim 22 wherein at least one channel intersects with at least one channel opening at an angle of about 0° relative to a horizontal axis of the valve stem.

25. A metering valve comprising:

a housing comprising an internal chamber defined by one or more chamber walls, the internal chamber comprising an outlet aperture;

a diaphragm positioned at the outlet aperture and in sealing engagement with at least a portion of the housing;

a metering gasket in sealing engagement with one or more chamber walls;

a valve stem comprising:

- i) a body comprising a body wall defining an internal chamber,
- ii) at least one inlet port through the body wall in fluid communication with the internal chamber,
- iii) a plurality channel openings in the body wall, each channel opening having a height and a width wherein at least two channel openings define a cumulative width, and wherein the cumulative width is greater than the height; and
- iv) at least one channel providing fluid communication between the internal chamber and each channel opening,

wherein the valve stem passes through the aperture in slidable sealing engagement with both of the diaphragm and the metering gasket; and

an annular space having a width defined by a distance between the chamber wall and the valve stem.

26. The metering valve of claim 25 wherein the height of at least one channel opening is from about 1 to about 5 times the width of the annular space.

27. The metering valve of claim 25 wherein the height of at least one channel opening is about 3 times the width of the annular space.

28. The metering valve of claim 25 wherein the height of at least one channel opening is from about 0.01 mm to about 1.0 mm.

29. The metering valve of claim 28 wherein the height of at least one channel opening is from about 0.1 mm to about 0.8 mm.

30. The metering valve of claim 28 wherein the height of at least one channel opening is about 0.25 mm.